MC0179

Department of Health
and Social Security

Welsh Office

March 1980

HMSO £7.50 net

HEALTH TECHNICAL MEMORANDUM

10

STERILIZERS

Polytechnic of North London
Library
Holloway Road, N7 8DB
(Telephone 01-607 2789)
Ext 2100

UNIVERSITY OF NORTH LONDON
WITHDRAWN

Book No 7738649
Class No 725.5 GRE
For Reference Only

LIBRARY AND INFORMATION SERVICE
POLYTECHNIC OF NORTH LONDON
HOLLOWAY ROAD
LONDON N7 8DB

POLYTECHNIC OF NORTH LONDON
CLASS No. 725.5 GRE
ACC. No. 7738649 Ref
+614.48
0113204582

28 MAY 1980

PN 7738649 3
725.5/GRE

Department of Health and Social Security: London

Welsh Office: Cardiff

Health Technical Memorandum Number 10

LIBRARY AND INFORMATION SERVICE
POLYTECHNIC OF NORTH LONDON
HOLLOWAY ROAD
LONDON N7 8DB

Sterilizers

Contents

Chapter *Page*

Introduction 2

1 **General**

1.1 Scope 3
1.15 Information 4
1.18 Safety 4
1.20 Definitions 4

2 **Policy and implementation**

2.1 Policy 5
2.17 Reference documents 6

3 **Types of sterilizers**

3.1 Sterilizers for porous loads 7
3.2 Sterilizers for fluids in sealed containers (bottled fluids sterilizers) 7
3.6 Sterilizers for unwrapped instruments and unwrapped utensils 7
3.7 Small electrically heated steam sterilizers for unwrapped instruments and unwrapped utensils 7
3.8 Hot air sterilizers 7

4 **Sizes of sterilizers and number required**

4.1 Sterilizers for porous loads 8
4.3 Sterilizers for fluids in sealed containers (bottled fluids sterilizers) 8
4.4 Sterilizers for unwrapped instruments and unwrapped utensils 8
4.5 Small electrically heated steam sterilizers for unwrapped instruments and unwrapped utensils 8
4.6 Hot air sterilizers 8

5 **Noise and vibration levels**

5.1 General 8
5.3 Mean near-field sound pressure level 8
5.7 Installation considerations 9

6 **Specifications to be included in hospital tender documents**

6.1 General specification 9
6.15 Particular specification 11

7 **Installation**

7.1 General 12
7.8 Ventilation 13
7.11 Steam service 13
7.17 Steam separator and pressure reducing valve 14
7.21 Safety valves 14
7.22 Water supply 14
7.24 Compressed air supply 14
7.25 Steam or air supplies for door seals 14
7.26 Drainage 14
7.30 Pipework arrangements 15
7.32 Commissioning procedure 15

8 **The testing of sterilizers**

8.1 Normal test procedures 16
8.4 Non-standard test procedures 16

9 **Procedure for dealing with defective sterilizers and reporting accidents**

9.1 General 16
9.3 Reporting defects 16
9.4 Reporting and recording accidents 16
9.5 Reporting explosions 16
9.6 Reporting to DHSS 17

10 **Maintenance and operating policy and procedure**

10.1 General 17
10.5 Maintenance and testing philosophy 17
10.8 Plant history record and sterilizer processing log 18
10.9 Routine cleaning and preparation 18
10.10 Temperature recorders and record charts 18
10.15 Maintenance—staff and training 19
10.18 Planned preventive maintenance (PPM) 19
10.23 Overhauls 20
10.24 Calibration of instruments fitted to the sterilizer 20
10.25 Air-tightness of the chamber 20
10.27 Air detection devices on porous load sterilizers 20
10.29 Stainless steel chambers 20

Digitized by the Internet Archive
in 2025 with funding from
UCL Library Special Collections

https://archive.org/details/ucl_mc0179

Chapter		*Page*
10.30	Maintenance of ancillary equipment	21
10.32	Steam generators	21
10.36	Return of sterilizers to service after maintenance	21
11	**Hot air sterilizers**	
11.1	Introduction	22
11.5	Recommendations in respect of hot air sterilizers for the National Health Service	22
11.10	Instrumentation and process control	22
11.14	Safety features required	23
11.19	Operating procedure	23

APPENDICES

1	Steam quality, wet loads and superheating	24
2	Instruments to be mounted on sterilizers and for testing and commissioning sterilizers	30
3	Planning information	43
4	Commissioning, operation and maintenance of sterilizers	48
5	Check-list of pre-commissioning procedures	56
6	Summary of sterilizer performance tests	57

Appendix		*Page*
7	Performance tests for porous load sterilizers	58
8	The Bowie/Dick tape test for porous load sterilizers	60
9	Leak rate test for porous load sterilizers	65
10	Air detector performance test for porous load sterilizers	66
11	Performance tests for sterilizers for fluids in sealed containers	68
12	Performance tests for sterilizers for unwrapped instruments and unwrapped utensils	70
13	Performance tests for hot air sterilizers	71
14	Typical master temperature record (MTR)	76
15	Maintenance certificate	79
16	Bibliography	80

CROSS-REFERENCES

Cross-references are indicated as follows:

Chapters and paragraphs:	Chapter 4 and 3.3
Appendices and paragraphs:	Appendix 2 and A 2.14
Bibliography:	suffix, e.g. (5)
Footnotes:	suffix, e.g. [a].

Health Technical Memorandum
Sterilizers

Introduction

This Technical Memorandum is intended as a guide for engineers, both specialists in sterilizers and sterilizing procedures, and those responsible for maintenance. It is also intended for pharmacists and sterile supply administrators. It is anticipated that the guidance will prove useful to supplies officers, architects, service engineers and to others not directly involved in sterilizers but who may have an interest.

This Memorandum does not give guidance on the scale of provision of sterilizers, since this must of necessity be established by a thorough study of the work load and specific requirements, and this will be covered in the HSDU Building Note.

1 General

Scope

General

1.1 This Memorandum gives guidance to hospital authorities in respect of the choice, purchase, installation, testing and commissioning, use and maintenance of steam sterilizers used for porous loads, fluids in sealed containers and unwrapped instruments and utensils. It gives similar guidance on electrically heated sterilizing ovens (hot air sterilizers). The term "Hot Air Sterilizers" is used alone in the chapters which follow.

1.2 Guidance on ethylene oxide sterilizers, low temperature steam and formaldehyde sterilizers and laboratory sterilizers will be published as addenda to this HTM at a later date.

1.3 A standard sterilizer processing log is under consideration, and it will be published as an addendum to this HTM.

1.4 THE STERILIZERS DESCRIBED IN THIS HTM MAY NOT BE SUITABLE (WITHOUT MODIFICATION) FOR SAFELY PROCESSING ARTICLES INFECTED WITH CATEGORY "A" PATHOGENS[(a)]. SUITABLE STERILIZERS FOR THAT SERVICE WILL BE DISCUSSED IN THE LABORATORY STERILIZER ADDENDUM.

Steam supply

1.5 Close limits have to be placed upon the quality of steam supplied for most sterilizing purposes. The problems are considered in depth in Appendix 1. Steam for sterilizers, other than those for bench top use, is normally obtained from the hospital mains. The disadvantage of other methods of steam raising are discussed in that Appendix. Independent steam generators should be used only where there is no practical alternative.

1.6 It is usually counter-productive to conserve energy by shutting off the steam supply to jacketted sterilizers during any part of the day or night during the normal week, and it is also preferable to keep the steam on to the jackets during the week-ends.

Instruments

1.7 The correct functioning of a sterilizer can best be monitored by the fitting and intelligent use of reliable instruments on the machine and by the use of other high quality instruments for the commissioning and periodic checking of the sterilizer and the instruments fitted to it. Appendix 2, which deals fully with all aspects of this subject, has been closely studied in conjunction with the sterilizer and industrial instrument industries.

1.8 It is essential that proper provision be made for the entry of thermocouples into the sterilizer chamber.

Installation planning

1.9 Appendix 3 indicates the space required around sterilizers for maintenance purposes and the services requirements for them.

1.10 Many technical advances have taken place in recent years in the design of sterilizers and their associated cycles. These advances will continue for many years to come. It is essential, therefore, that sterilizers for a particular scheme are not ordered and stored on site for long periods but are delivered, installed, commissioned and put into service with the minimum of delay. Failure to observe this procedure will often result in the installation of a technically obsolete sterilizer.

Product quality control

1.11 Continuous control of the sterilizing cycle can be based upon the intelligent use of instruments, careful commissioning, the adoption of a properly designed PPM programme and the regular comparison of temperature records of production cycles with corresponding records obtained during commissioning. This requires close and continuous collaboration between the Sterilizing Engineer, the Maintenance Engineer and the User. This subject is covered fully in Appendix 4. Guidance concerning the sterilization of medicinal products has been issued by the Chief Pharmacist and is also given in "Guide to Good Pharmaceutical Manufacturing Practice 1977" (GPMP) (2).

Commissioning

1.12 This is covered in paragraphs 7.32–7.34. Appendix 5 is a check-list of pre-commissioning procedures and commissioning tests; all other tests are covered in Appendices 7–13.

Operation and maintenance

1.13 Appendix 4 deals with this subject in considerable detail, reinforcing Chapters 9 and 10.

The testing of sterilizers

1.14 Appendix 6 summarizes all tests required on sterilizers. Appendices 7 to 13 describe in detail the various tests required for porous loads, fluids, unwrapped instruments and utensils and hot air sterilizers.

(a) See DHSS—Report of the Working Party on the Laboratory Use of Dangerous Pathogens—Sir George Godber, May 1975 (1). These are described in the report as:

"Organisms so dangerous as to present great risks to the health either of laboratory workers or of the human or animal communities such that material containing live organisms should not be accepted knowingly or held at all in this country without authorisation".

Information

1.15 Much of the technical content of this memorandum evokes principles promulgated in many British Standards. The specific British Standards covering sterilizers are currently under review, and it should be noted that this publication and the B.S. derive information from some common sources.

1.16 Managerial aspects of sterilizers were considered in the "Collingwood" Report (3)—HM(67)13—Central Sterile Supply Departments (4), and much of the additional material in the Memorandum has been written to give effect to this Report.

1.17 The "Guide to Good Pharmaceutical Manufacturing Practice 1977" (2) emphasises much of the advice contained herein.

Safety

1.18 "The cause of this disaster is to be found in human failings . . . ranging from simple carelessness to poor management of men and plant. The Committee heard of no imminent technological advance in the field of production of intravenous fluids which will eliminate the need for skilful men devoted to their work . . . Too many people believe that sterilization of fluids is easily achieved with simple plant operated by men of little skill under a minimum of supervision. . . Safety depends ultimately on untiring vigilance . . ." CLOTHIER COMMITTEE REPORT, JULY 1972 (5)—Extract from Principal Conclusions.

1.19 The integrity of all products processed in a sterilizer is ultimately dependent upon "untiring vigilance". This truism in respect of operator safety is particularly significant with the introduction of the Health and Safety at Work, etc. Act (1974) (6). Steam sterilizing necessitates complicated cycles. Protection is afforded in the first instance by "fail safe" design principles, some of which also provide protection of the product by indicating an ineffective cycle. However foolproof in design, any safety device can be defeated, either wantonly or accidentally. In this area "vigilance" will necessitate skilful personnel, fully trained in the field of sterilizers.

Definitions

1.20 Terms and abbreviations used in this HTM have the following definitions:

Data Sheets	DHSS Engineering Division Specification Data Sheets CS21[a].
Sterilizer Engineer	This person should have a specialist knowledge of sterilizers and sterilizing procedures. He will be required to liaise closely with professionals at various levels, and it is preferable that he should be a chartered engineer. His appointment, whether from Regional or Area staff, is a matter for agreement between the Authorities concerned, bearing in mind the legal responsibilities of the Area Authority. It is considered that the balance of advantage—both in technical and economic terms—will be with a Regional appointment, but it is necessary that all Sterilizer Engineers be appointed in writing by name and that the appointment be made known to all interested parties.
Maintenance Engineer	This person should be a responsible engineer of the Area Health Authority (often the Hospital Engineer). He should be conversant with sterilizers and have received specific training[b] on sterilizers and their maintenance. (He will usually have other duties in the hospital, District or Area in addition to those related to sterilizers.)
Production Manager	This person may be the Production Pharmacist. See Chapter 4 of "Guide to Good Pharmaceutical Manufacturing Practice 1977" (GPMP) (2).
Quality Controller	Also see Chapter 4 of GPMP.
Medicinal Product	As defined by Medicines Act 1968, Section 130 (7).
User	This person should be nominated by the Area Health Authority, as appropriate, to each sterilizer or group of sterilizers. The person is responsible for the management of the unit in which the sterilizer is installed and could be the sterile supplies administrator, head of laboratory, theatre sister, production pharmacist, production manager or other responsible person. In some cases the User may nominate one or more Plant Operators to have the immediate responsibilities related to the loading and unloading of the sterilizers, the recording of the sterilizer instrument readings and simple "housekeeping" duties as defined in Appendix 4.

(a) The current edition is dated March 1971 and it will be revised to correspond with this revision of the HTM.

(b) Training is available at Falfield (see definition).

Plant operator	Any person who operates a sterilizer.
Batch	The contents of one load of a sterilizer ("batch" and "load" are synonymous in this document).
Falfield	The Hospital Engineering Centre, Eastwood Park, Falfield, Wotton-under-Edge, Gloucester, GL12 8DA. Telephone No. Falfield (STD 04548) 207. (All correspondence to be addressed to the Principal.)
ESTMANCODE	DHSS publication "Estate Management (Building, Engineering and Grounds) Practices Code for the NHS" (8). (In the context of this HTM the reference is to Chapter II, Section 2, previously published as Hospital Technical Memorandum No. 13—Planned Preventive Maintenance: A system for Engineering Plant and Services (9).)
PMG/12	A maintenance manual, associated with ESTMANCODE, covering planned preventive maintenance tasks for electrical equipment (10).
PMG/13	As for PMG/12 but for mechanical equipment (11).
GPMP	"Guide to Good Pharmaceutical Manufacturing Practice 1977" (2).
PPM	Planned preventive maintenance.
TRC	Temperature recorder chart; a completed chart recording from a temperature recorder fitted permanently to the machine.
MTR	Master temperature record. An MTR is required for each type of batch of medicinal products processed by a fluids sterilizer and each type of load processed by a hot air sterilizer as agreed by the User. An MTR is not normally required for a porous load sterilizer nor for a sterilizer for unwrapped instruments and utensils except for reference by engineers. It is a transparent 1 : 1 undistorted copy of an acceptable temperature record chart obtained by the Sterilizer Engineer after satisfactory commissioning by the Contractor, or subsequently. The original is retained with the commissioning documents by the Sterilizer Engineer. A new MTR is also required after any sterilizer used for processing medicinal products and any hot air sterilizer is re-commissioned. A typical example is given in Appendix 14.
SALINE	Solutions of chloride salts such as are processed in sterilizers described in this Memorandum.

1.21 **Abbreviations for departments with centralized sterilizing functions**

TSSU—Theatre sterile supply unit.
CSSD—Central sterile supply department.
HSSU—Hospital sterile supplies unit.
SASD—Sterile and associated supplies department.
HSDU—Hospital sterilizing and disinfecting unit.
TSC—Theatre service centre.

2 Policy and Implementation

2.1 Department policy is outlined in the Report prepared by the Joint Committee of the Central and Scottish Health Service Councils on Central Sterile Supply Departments issued under HM(67)13, dated 6 March 1967 (4). Both HM(67)13 and Hospital Building Note 26—Operating Department (12) recommend that all theatre instruments and utensils should be sterilized centrally, either in a Theatre Sterile Supply Unit (TSSU) or in a Central Sterile Supply Department (CSSD).

2.2 The Report recommends that a consultant microbiologist be nominated to exercise clinical responsibility for each CSSD. It is current policy to recommend such cover in any sterilizing unit.

2.3 The Report reinforces the Department's warning against the use of boiling water "sterilizers", confirming that they are ineffective and should be removed.

2.4 The requirements of the Medicines Act 1968 (7) apply to sterilizers processing certain medicinal products, and in this connection reference should be made to the DHSS publication "Guide to Good Pharmaceutical Manufacturing Practice 1977" (2).

2.5 It is undesirable to install sterilizers designed for more than one process, e.g. both textiles and fluids, both steam and ethylene oxide.

2.6 There are five principal classes of load to be sterilized in the National Health Service:

a. Porous loads.

b. Fluids in sealed containers.

c. Unwrapped bowls and instruments.

d. Equipment and materials for aseptic manufacture of medicines.

e. Materials associated with Specific Pathogen Free (SPF) procedures.

2.7 The use of sterilizers with a door at each end assists in the segregation of processed from unprocessed batches, but only in exceptional circumstances, e.g. for loads in categories 2.6d and 2.6e above, is it necessary to use a sterilizer with a door at each end. Since maintenance problems are much less with single door models, their use with a proven segregation system is to be recommended. Sterilizers with the chamber lifted vertically from a fixed bedplate may be considered when large quantities of soft packs are to be processed.

2.8 Sterilizers of the same class in a particular installation should generally be of the same size and made by the same manufacturer.

2.9 It is normal practice for the manufacturer of the sterilizer to be either the contractor for the supply only or for the supply, installation and commissioning of the machine. Where the term "manufacturer" is used in this document it is to be construed as if it includes the obligations of the contractor.

2.10 The importance of close and continuing collaboration between engineers and those responsible for the production of sterile supplies, including sterile medicinal products, cannot be too highly stressed. The production of many such products is covered by the Medicines Act 1968 (7).

2.11 Reserve sterilizing capacity should always be available, so that it is possible to withdraw a sterilizer for planned maintenance purposes and periodic testing in normal working hours without jeopardizing production; production schedules should be arranged accordingly.

2.12 Ethylene oxide sterilization is considered suitable for hospital use only at a few centres where specialist microbiological testing and quarantining can be assured by each Regional Health Authority. The advice of the Scientific and Technical Branch of the Department should be sought when such a centre is planned. The process is potentially hazardous.

2.13 Consideration must be given to the use of a CSSD or other similar centralized service before replacing any porous load sterilizer which is not in a centralized sterilizing department, and before purchasing any new porous load sterilizer for use anywhere else in a hospital.

2.14 The inter-relation of the duties of the "Sterilizer Engineer", the "Maintenance Engineer" and the "User" are referred to in Appendix 4.

2.15 Further advice on sterilizers may be obtained from:

a. Directorate of Works Operations, Branch 3.1.2, Euston Tower, 286 Euston Road, London, NW1 3DN (Telephone 01–388 1188).

b. Supply Division DHSS, Scientific and Technical Services Branch, STB 4A, 14 Russell Square, London, WC1B 5EP (Telephone 01–636 6811).

c. Scientific and Technical Services Branch, Common Services Agency, Supplies Division, Trinity Park House, South Trinity Road, Edinburgh, EH5 3SH (Telephone 031–552 6255).

2.16 Administrative arrangements and other aspects outlined in this HTM may be different in Scotland, Wales and Northern Ireland, e.g. in reference to the duties of Sterilizer Engineers.

Reference documents

2.17 The British Standards Institution, 2 Park Street, London, W1A 2BS, has published the following standards in respect of sterilizers for hospital use:

B.S.2646: 1955	Copper laboratory autoclaves (13).
B.S.3421: 1961	Performance of electrically heated sterilizing ovens (14).
B.S.3970 Part 1: 1966	Sterilizers for porous loads (15).
B.S.3970 Part 2: 1966	Sterilizers for bottled fluids (16).
B.S.3970 Part 3	Sterilizers for unwrapped instruments and utensils (17).
B.S.3970 Part 4	Small electrically heated steam sterilizers for unwrapped instruments and utensils (18).
B.S.3970 Part 5: 1968	Electrically heated steam generators for use with hospital sterilizers (19).

B.S.2646 is being revised. B.S.3970 Parts 3 and 4 were issued in draft form only, and the B.S. as a whole is being revised.

2.18 Sterilizing ovens conforming with B.S.3421 are not automatically controlled. Sterilizers conforming with all parts of B.S.3970 are automatically controlled.

2.19 Intending purchasers of sterilizers are recommended to study the current editions of the relevant British Standards in conjunction with this Memorandum and to make use of the Department's Engineering Division Data Sheets CS21—STANDARD SPECIFICATION—STEAM STERILIZERS. The guidance of the Department of Health and Social Security should be sought before a decision is taken to purchase a sterilizer of a type not in accordance with the guidance given in this Memorandum.

2.20 Certain documents referred to are only available from the Department, e.g. ESTMANCODE, Data Sheets, "Health Service Estate".[a]

2.21 This revision of the Hospital Technical Memorandum is being issued at a time when the relevant British Standards are being revised or considered for revision. It contains the current views of the Department on the most appropriate technical points for any revised British Standard. Further guidance will be issued by the Department if any discrepancy arises between the HTM and a revised British Standard. Engineering Division Data Sheet Specification CS21, dated March 1971, is being revised to agree with the guidance herein.

(a) Formerly known as "Hospital Service Engineering".

3 Types of sterilizers

Sterilizers for porous loads

3.1 These sterilizers are intended to deal with dressings, textiles, equipment made of rubber, e.g. gloves, wrapped instruments and wrapped utensils. Sterilizers in this category must have means to remove air from the chamber and load prior to the admission of steam for sterilization, and to dry the load under vacuum after sterilization.

Sterilizers for fluids in sealed containers (bottled fluids sterilizers)

3.2 Although the 1966 edition of B.S.3970 (15–19) stipulates that these must be of rectangular form, the DHSS is prepared to approve some with cylindrical chambers. The Standard makes provision for the fitting of the following optional extras:

a. means to accelerate cooling by the use of cooling water sprayed over the fluids containers;

b. means for the sterilization of fluids in plastic bags by maintaining equilibrium pressure conditions between the inside and outside of the bags ("air ballasting").

3.3 When accelerated cooling and/or "air ballasting" systems are used it is essential to establish that the containers will remain sealed throughout the process.

3.4 It is a requirement of B.S.3970 that it should not be possible to open the door of a sterilizer until the temperature of the contents of the containers has fallen below 80°C. FAILURE TO OBSERVE THIS REQUIREMENT HAS LED TO SERIOUS ACCIDENTS RESULTING FROM THE EXPLOSION OF CONTAINERS. Fluids in some non-rigid containers do not present the same hazard, and it may be necessary to remove them from the sterilizer at a temperature in excess of 80°C for operational reasons. Any new standards will take account of this situation.

3.5 The Scientific and Technical Services Branch should be consulted before a specification is prepared for a sterilizer employing mixtures of air/steam/water for sterilizing fluids in non-rigid containers. It is not recommended that sterilizers be ordered suitable for conversion for processing non-rigid containers at a later date.

Sterilizers for unwrapped instruments and unwrapped utensils

3.6 Instrument and utensil sterilizers are intended to deal with unwrapped instruments and unwrapped utensils within a complete cycle time of approximately 10 minutes. Certain machines which are available, operating at 150°C (3.45 bar) held for a few seconds, do not comply with the essential requirements of the British Standard, and in practice the time saved in sterilizing is lost in waiting for the temperature of the load to fall to a level at which the sterilized item can be used; their use is not, therefore, recommended.

Small electrically heated steam sterilizers for unwrapped instruments and utensils

3.7 These are normally used for similar duties to those in 3.6 above but have internal steam raising equipment and the cycle time may be longer; for example, a cycle may take 20 minutes from cold. The sterilizers are free-standing and do not require any piped services. Demineralized or distilled water, e.g. purified water BP, must be used in them and they must not be allowed to boil dry.

Hot air sterilizers

3.8 These are referred to for first time in this edition of the HTM. Chapter 11 briefly discusses their principles and use. They are dry air ovens, operating at ambient pressure and should comply with B.S.3421 (14) except as indicated in Chapter 11; in particular, it is recommended that they be automatically controlled and be fitted with door locks.

4 Sizes of sterilizers and number required

Sterilizers for porous loads

4.1 It is difficult to give precise information on the types and sizes of sterilizers required for particular hospitals because in practice there are very substantial variations in patterns of use. It is recommended that, when assessing the number and size required, the bulk volume of the workload to be handled should, if possible, be measured, e.g. by reference to the present source of supply or sterilizing. The size and number of sterilizers necessary can then be calculated having regard to the workload, bulk volume and the number of productive cycles which are practicable within the intended working hours. A porous load sterilizer conforming to B.S.3970 (15) is required to complete its cycle of operations in not more than 30 minutes. The drying stage time is, however, sometimes extended when the sterilizer is used for processing trays of instruments and other difficult loads. If the total cycle time is to be extended, this must be allowed for when calculating the number of sterilizers required. The preferred size for porous load sterilizers is 600 litres (21 ft^3), 600 mm wide (24 in.) × 900 mm high (36 in.).

4.2 Some guidance on the provision of sterilizers for CSSDs and TSSUs will be found in Hospital Building Notes 13 (20) and 26 (12) respectively.

Sterilizers for fluids in sealed containers (bottled fluids sterilizers)

4.3 It is generally accepted that the best method of providing sterile fluids is by the use of individual containers, e.g. 1 litre and 500 ml. bottles. The size of sterilizer required will be determined by the number of containers to be sterilized in a given time. The daily load may be dealt with in one cycle of several hours' duration or by several shorter cycles, using a rapid cooling device. If a rapid cooling device and/or air ballasting is required, this must be specified in the invitation to tender.

Sterilizers for unwrapped instruments and unwrapped utensils

4.4 Where, in existing hospitals, separate sterilizers are required for individual theatres, one sterilizer 460 mm. diameter by 760 mm. long and complying with B.S.3970 (17 and 18) is generally sufficient to meet the needs of a single operating theatre.

Small electrically heated steam sterilizers for unwrapped instruments and utensils

4.5 These usually have cylindrical chambers, and the most commonly used machine has a chamber 200 mm. diameter and 300 mm. long. They are generally fitted with up to 4 removable trays about 150 mm. × 300 mm. These sterilizers may be used in theatre suites (1 per pair of theatres) where there is no TSSU, and in certain clinics.

Hot air sterilizers

4.6 The chamber size of the oven most suitable for use in the NHS is 450 mm. × 450 mm. × 400 mm. In any specialist unit where there is a high usage of this type of equipment (e.g. Ophthalmology) the demand would be met by a number of units of this size.

5 Noise and vibration levels

General

5.1 The overall noise level anywhere in a room containing the sterilizer(s) should not exceed the following levels for more than 10 per cent of the time:

a. CSSD: 70dBA

b. operating theatre suites, pharmacies and treatment rooms: 55dBA

c. other noise sensitive areas: 60dBA.

5.2 In non-sensitive areas the maximum noise level anywhere in the room should not exceed 85dBA. The above levels are for an area or space when the sterilizer is operating under the normal working conditions. The levels include noise from *all* sources including the sterilizer.

Mean near-field sound pressure level

5.3 The mean near-field sound pressure level of each sterilizer should be determined in accordance with B.S.4196 (21). The only plant functioning during the test should be that required for the correct and complete operation of the sterilizer. All other equipment should be inoperative.

5.4 The mean near-field sound pressure level should be found for the noisiest part of the sterilizer cycle from at least five readings on a reference radius of 0·3, 1·0, 3·0 or 10·0 m. centred on the geometric centre of the equipment. The reference radius should be less than twice the leading dimension of the equipment or that part of the equipment being tested. In the case of built-in sterilizers the geometric centre should be that of the projection into the user space, and the leading dimension will be the projection from the fascia.

Note: Transient noise of less than 5 seconds duration, i.e. between different parts of the cycle, may be ignored.

5.5 The measured mean near-field noise level of the sterilizer should be less than the general levels given in 5.1 above when reduced as appropriate as follows:

a. generally, if there are only one or two pieces of major noise producing equipment, not necessarily all sterilizers, operating at the same time in the room under consideration, the reduction should be 5 dBA for each sterilizer;

b. if there are three noisy items the reduction should be 7 dBA;

c. for four and five items: 8 dBA;

d. for six items: 9 dBA;

e. for seven or more: 10 dBA.

5.6 In plant rooms and industrial areas the noise quality will not be critical, but a further requirement should be stated when the noise level will affect areas requiring a good acoustic environment. For example, in patient areas and operating theatres the noise should not contain any significant discrete frequency. From the mean near-field sound-pressure level measured in 5·4 above, discrete frequency components will be judged to be present and predominant in a 1/3 octave band if a 1/3 octave sound-pressure level in any of the mean near-field sound-pressure level measurements in the range 50–12500 Hz exceeds the arithmetical average in the two adjacent 1/3 octave bands by more than the amount shown in the table.

1/3 octave band mid-frequency Hz	63–100	125	160	200–250	315–10000
Difference not to exceed dB	6	5	4	3	2

It is usually unnecessary to carry out this test except when tonal components can be detected by ear, when it therefore becomes necessary to prove that the contract specification has been met.

Installation considerations

5.7 The room in which the sterilizer is to be installed should be planned and designed so that the noise transmitted from the room does not give rise to excessive noise levels in adjoining areas.

5.8 Open louvres in walls and internal doors should be avoided if the sterilizer room is in or adjacent to a main building or a noise sensitive area. In such situations doors should be self-closing and a good fit in their frames, preferably with compressed rubber seals. This may prevent natural ventilation, and mechanical ventilation may therefore be required as detailed elsewhere. The need for such a solution can usually be avoided in the planning stage. The fascia panel cannot always be relied upon for sound attenuation, e.g. when it incorporates louvres or sliding doors.

5.9 The total vibration transmitted through the supporting feet and service connections to the building structure should not exceed the amplitudes given in the table below at any part of the cycle or under any load condition:

Octave band mid-frequency Hz	*Maximum acceptable vibration amplitude* mm.
2	0·04
4	0·025
8	0·014
16	0·007
32	0·003
63	0·001

Note: Transient vibrations of greater amplitude than those above may be tolerable if of short duration.

5.10 If vibration is likely to be a problem in a particular situation it is recommended that:

a. the whole sterilizer assembly be secured on properly designed anti-vibration mounts;

b. vibration transmission through service connections should be avoided by the use of suitable flexible connections;

c. pumps and motors associated with sterilizers should be resiliently mounted whether or not they are integral with the main unit.

6 Specifications to be included in hospital tender documents

General specification

6.1 The specification should state that the sterilizer must comply with the appropriate British Standards and with any additional requirements as indicated in this revision of the Memorandum. It is strongly recommended that use should be made of the Department's Engineering Data Sheets CS21 which are intended to form Section 3 of a complete standard specification. *Guidance Notes* to facilitate specification of the details are included in the Data Sheets.

6.2 Hot air sterilizers should meet the specification for Performance of Electrically Heated Sterilizing Ovens in B.S.3421 (14) except that the maximum error of the thermometer should be in accordance with Appendix 2, paragraph A 2.9. These sterilizers should

also be fitted with high temperature limit switches and the doors should be lockable.

6.3 All invitations to tender for sterilizers should request full information from the manufacturers[a] on all services and connections to be provided by the hospital for operating the sterilizers. Manufacturers should also be required to state the maximum flow rates, the minimum and maximum acceptable pressure and the maximum consumption of each service for one cycle of the largest load. The services required may include the following:

a. steam supply (see Appendix 1);

b. electricity—the specification should state the type of supply available, i.e. voltage, frequency and number of phases (local or integral steam generators usually result in a high electrical loading);

c. water supply for condensers, water sealed pumps and occasionally for rapid cooling devices on sterilizers for bottled fluids (the fitting of temperature limiting valves and other devices to reduce water consumption should be encouraged—see also 7.22);

d. condensate return from the jacket, steam separator and traps;

e. open gravity drain, except for effluent containing harmful gases or pathogenic material, in which case special closed and protected drainage systems may be necessary;

f. waste cooling water outlets from condensers;

g. compressed air (air ballasting on some bottled fluids sterilizers and for air operated valves or other mechanisms on some sterilizers).

6.4 The manufacturer should state the heat energy released under continuous full load operating conditions when the ambient temperature in the adjoining rooms is 20°C in a period of one hour in:

a. the operating area;

b. the maintenance area.

6.5 The controls and instruments must function correctly under the worst summer conditions, i.e. 40°C in the plant room.

6.6 The manufacturer should be given sufficient information to enable him to confirm that the noise and vibration level after installation will not exceed that specified for the location, as in Chapter 5.

---

[a] It is normal for the manufacturer of the sterilizer to be the contractor for its supply and/or installation. The term "manufacturer" in this HTM relates to the manufacturer as such or in his capacity as contractor. In this HTM the term "contractor" is used when it specifically refers to the manufacturer in his capacity as a contractor, in particular as an installation contractor (or sub-contractor).

6.7 Clear and simple instructions for operating the sterilizer should be prominently displayed in indestructible form and preferably on or near the operating panel. These instructions should be suitable for the guidance of staff unfamiliar with the machine.

6.8 The type and standard of packing for delivery of the sterilizer should be specified, unless the manufacturer is to be responsible for the installation of the machine (the preferred arrangement).

6.9 Consideration must be given to the probable conditions of installation (e.g. whether the machine will be installed and used at once or will be positioned adjacent to building operations in dusty conditions, or will stand on the site unconnected for a long period). It may be necessary in some cases to specify dustproof packing and a substantial transit case to prevent damage on site.

6.10 The manufacturer should be required to supply two complete sets of technical literature on the operation, maintenance and overhauling of all major functional items of equipment incorporated in the sterilizer, as well as two copies of record drawings showing the pipework and electrical circuits on the machine itself. This should indicate all parts which should be held in stock and may require replacement during the normal working life of the sterilizer. The literature must include a complete PPM programme, frequencies being consistent with those embodied in the standard NHS PPM scheme. Thus it must show the tasks to be performed weekly, three-weekly, six-weekly, quarterly, half-yearly, yearly and multi-yearly. The manufacturer must also supply insurance test certificates as appropriate.

6.11 The manufacturer should also be required to provide, at the time of tendering, details of routine tests suitable for determining the sensitivity of the air detectors fitted to porous load machines made by him and details of any extra device required to be supplied or fitted by the user for the purpose of conducting the test.

6.12 Adequate arrangements will be required for the regular servicing of sterilizers, and early consideration should be given to the nature of the arrangements. If contract servicing is necessary, enquiries on the terms and conditions of a suitable contract should be made at the time when the tenders are issued.

6.13 The manufacturer should be required to tender for quarterly maintenance inspections during the first year and to submit written reports promptly on the result of each inspection, unless this is automatically provided under the guarantee. The contract will not normally cover daily, weekly, three-weekly or six-weekly maintenance, which must start at hand-over.

6.14 The manufacturer should be required to undertake to replace, free of cost to the purchaser, any part

of the sterilizer found, within 12 months of the handing-over date, to be defective due to faulty materials or workmanship or poor design.

Particular specification

6.15 The specification should be based on the Standard Specification Data Sheets CS21, amended as necessary to conform with the requirements of this Memorandum.

6.16 Adequate details of the design of the proposed location of the sterilizer and the appropriate noise level should be stated clearly in the specification.

6.17 Side, back and top panels of free-standing sterilizers should be easily removable and replaceable for maintenance purposes.

6.18 Power-operated doors are desirable on porous load and fluids sterilizers of 300 litres (10 ft.^{3}) capacity and over. Designs at present available are:

a. sliding doors (vertical or horizontal);

b. side-hinged doors;

c. fixed bed-plate (or door) with a chamber which is raised vertically.

6.19 In 6.18a and 6.18c the possibility of the operator touching the hot inside face of the door is reduced. Other considerations may influence the choice of door operating system in any particular installation, e.g. work load, space restrictions, price and ease of maintenance. Vertical chamber sterilizers require special guards to ensure the safety of the operator when the chamber is being lowered.

6.20 If the capacity of the sterilizer chamber exceeds 600 litres, a device should be fitted so that the door can be secured open by a lock, the key of which can be removed and kept by a person entering the chamber. Alternative locking arrangements may be used if they are approved by the Health and Safety Executive (HSE).

6.21 The door control mechanism should incorporate a safety device which will prevent the entry of steam until the door is fully closed and secured. This feature should remain operative at all times, including during a manual operation of the machine and/or failure of any service to the machine. The requirement does not apply to sterilizers in which steam is generated within the chamber itself.

6.22 All safety devices associated with the opening, closing or locking of the door, or with the admission of steam and whether manually, electrically, pneumatically, hydraulically or mechanically operated must fail safe. The Health and Safety at Work Booklet 24, "Electrical Limit Switches and their Application" (22) gives valuable advice on this matter. Where doors are secured by one or more threaded bolts, a device should be attached to one or more of the bolts (preferably opposite the hinge) which partially opens the door as the bolt is unscrewed; the door seal is thus broken before all the bolts are fully disengaged. It may not be practicable to modify all existing machines to meet certain of the requirements in this paragraph. The advice of the HSE Inspector should be sought in such cases.

6.23 The specification for any sterilizer required to have a door at each end should ensure that it meets the following additional requirements during normal operation:

a. it should not be possible to have both doors open at the same time;

b. having for any reason opened and then closed the loading door, it should not then be possible to open the unloading door until the machine has satisfactorily completed the sterilization cycle;

c. it should only be possible to open or close a door at one end of the sterilizer by operating the controls at that end;

d. the automatic process control should be operated from one end only;

e. a device should be provided at each end of the sterilizer indicating "DOORS LOCKED" when both doors are closed and secured;

f. the following should be provided at the unloading end in addition to any process indication fitted at the loading end of the sterilizer:

(i) chamber pressure gauge;

(ii) a device indicating "STERILIZING" during the whole of the process;

(iii) a device indicating "PROCESS COMPLETE".

These signals should be cancelled at or before the opening of the unloading door.

Note: The machines will be installed for unidirectional flow.

6.24 If hinged doors are required, the specification should state whether these are to be hinged on the left-hand or right-hand of the opening when facing the machine, or whether either is acceptable.

6.25 The door should be readily accessible for cleaning, adjustment and replacement.

6.26 Sterilizers designed to be built into a pre-formed recess are not necessarily made so that there are no

gaps between the front and the rear of the unit. Exceptionally, where it is necessary that the area in which the sterilizer is operated must be completely sealed from the machine maintenance area to prevent the transfer of micro-organisms (e.g. for animal research laboratories) the requirement must be clearly stated in the specification.

6.27 In the event of a sterilizing stage failure on an automatically controlled machine a "NON-STERILE" sign should automatically be illuminated and an audible alarm should sound. A switch may be provided to mute the alarm but it should NOT extinguish the illumination of the sign until the door is released. The door must be so interlocked that on a sterilizing failure it will not be released until some special manual action has been taken. This usually involves the use of a key.

6.28 Any control which is variable but pre-set should be accessible only to authorised persons.

6.29 Means must be incorporated to enable the Maintenance Engineer or other authorized person to carry out the Leak Rate Test without difficulty on porous load sterilizers.

6.30 All exposed wiring at mains voltage on the machine should be carried out with mineral insulated copper sheathed cables with overall PVC sheath, or an approved equivalent, in accordance with the Institution of Electrical Engineers' Regulations for Electrical Equipment of Buildings (23). Exposed extra low voltage wiring may be carried out in PVC cable conforming with B.S.6231 (24) provided it is suitably protected against mechanical damage and the effects of its environment.

6.31 Appendix 2 gives details of all instruments required to be fitted on sterilizers, and also the instruments to be used for testing, commissioning and periodically checking the accuracy of the instruments fitted on the sterilizers.

6.32 Where a rapid cooling device is needed, the specification should require the manufacturer to state the means by which the system may be flushed and the frequency at which such flushing operations should be carried out. Manufacturers should also be advised that it is desirable for the flushing operation to be carried out by the user without assistance from the engineering staff. On some machines a push-button flushing cycle can be provided at a relatively small extra cost.

6.33 Where practicable, the chamber and all pipework, ancillary equipment, the outer surfaces of doors and exposed panels in the working area should be insulated to ensure a surface temperature not exceeding 40°C under continuous operating conditions with an ambient temperature of 20°C. It is desirable that the thermal insulation be easily removable and well protected to prevent flaking during removal and replacement. Asbestos products should not be used. The insulation should have a flame rating of Class O as defined in Building Regulations 1976, Clause E15 (25).

6.34 The manufacturer should be required to provide a suitable steam pressure reducing valve or valves, with a separator on the high pressure side of each reducing valve. The vessel should be protected by means of pressure relief valves fitted to the chamber and/or jacket.

6.35 The manufacturer should fit a valve or cock adjacent to each steam pressure gauge on the sterilizer in a vertical position, suitable for the installation of the test gauge.

6.36 Any strainer in the steam, condensate, drain or water lines must be located in a readily accessible position. Strainers in chamber drains should be properly secured.

6.37 Air for ballasting must be oil-free; a suitable specification for the air is at paragraph 5.6.3.1 of B.S.4275 (26). Air for controls must be dry and clean. The sterilizer manufacturer must fit any air dryer, oil eliminator and filter on the machine in a position where it can readily be serviced.

6.38 Steam and condensate pipework on the sterilizer should be arranged so as to exclude, as far as practicable, any deadlegs or pockets in which water can be retained when the machine is not in use. On fluids sterilizers all condensate pipework and water circulating systems should be self draining; alternative means of draining must be provided where this is impractical.

6.39 The manufacturer should be informed that after installation each sterilizer will be submitted to a series of tests including functional acceptance tests. These tests may have to be deferred until a considerable time after the sterilizer is installed. The required tests should be set out in detail in the specification. Whenever it is feasible to do so, there should be a clear statement of the date when it is expected that they will be witnessed for the purchaser, and of the date by which all services will be available, so that the contractor will be well aware of his responsibilities and can provide accordingly in his offer.

7 Installation

General

7.1 Sterilizers should be sited and installed after careful planning, when the problems associated with access for installation and removal, floor loading, the provision of steam and other services, maintenance and ventilation have been fully examined. The Sterilizer Engineer and the Maintenance Engineer should be consulted throughout the planning and purchasing

stages. Advice may also be sought from the Directorate of Works Operations Branch 3.1.2 and the Scientific and Technical Branch of the Supply Division of the Department of Health and Social Security or from corresponding authorities in Scotland, Wales and Northern Ireland.

7.2 The variation in details of different manufacturers' designs are not significant for planning purposes except in the case of one porous load sterilizer, the chamber of which is raised vertically. Appendix 3 gives planning data covering space requirements (including space required for maintenance purposes) and services requirements. The information is intended as an initial guide for planning purposes. It does not cover the space required in front of the machine, but adequate circulating space must be provided for the manoeuvring of the loading carriages where these are used.

7.3 Where the sterilizer is built-in, provision should be made for maintenance staff to gain access to the maintenance area without having to enter the sterilizing room. Provision should also be made for convenient access from the maintenance area to the front panel of the sterilizer. The vertical chamber machine referred to in 7.2 is normally in the sterilizing room.

7.4 When a sterilizer with a door at each end is installed, arrangements for maintenance should, as far as possible, be for main access from the "dirty" end, but adequate access will be necessary to both sides of the sterilizer.

7.5 Most machines do not require special foundations. Careful attention must be paid to height adjustment, especially where several machines are to be served by a common loading carriage system, and also to effective drainage from chamber and jacket. Attention must be paid to the noise attenuation problem when the foundations are designed (see Chapter 5). Attention should be drawn to the thickness of the fascia panel and to any obstructions which will interfere with the loading carriage, etc. An excessively thick recess wall may be a hindrance to maintenance work.

7.6 The adverse effects of excessive heat on the electronic, electrical and pneumatic systems and instruments are emphasized (see 6.4).

7.7 The engineering services to sterilizers should be provided by others and terminated within the plant room by valves and isolators normally within 2 m. of the sterilizer, the size and location of the terminations having been previously agreed with the Sterilizer Engineer. This will allow the contract with the sterilizer manufacturer to include only for the supply, delivery, off-loading and transportation on site, installation, testing and commissioning of the sterilizer within the plant room.

Ventilation

7.8 Careful attention must be paid to ventilation of the sterilizing room and the maintenance area: the obvious advantage of a location with an outside wall should not be overlooked. The rate of air change required for this purpose must be related to the heat loss from the plant as well as to the vapour produced in and around it. The high temperature and humidity in the vicinity of sterilizers will produce uncomfortable working conditions and may have an adverse effect on some types of automatic control equipment. The ambient temperature in the plant room, with all plant running normally, should not be allowed to exceed 40°C under the worst summer conditions.

7.9 Excessive water vapour discharging from the chamber into the sterilizing room when the door is opened should be collected at high level and extracted to outside.

7.10 Current experience indicates that a 400–600 litre sterilizer with the door closed will release approximately 0·5kW into the sterilizing room by radiation and convection from the machine and 3·5kW into the maintenance area. Where sliding door machines are mounted behind a fascia panel almost all this heat is released into the maintenance area. With the door open additional heat into the user space might typically be 2·5kW for a side hinged door and 1·5kw for a sliding door.

Steam service

7.11 Arrangements should be made for the steam service system to be thoroughly examined and for any defects to be remedied before a sterilizer is put into service. Further notes on this subject are in Appendix 1. A pressure gauge should be fitted on the service main in the plant room or equivalent place.

7.12 It must be emphasized that a continuous supply of steam with a dryness fraction of approximately 0·9 and at 3·5/4·0 bar pressure is required if steam sterilizers conforming to B.S.3970 (15–19) are to operate correctly. There is evidence that excessive fluctuation of steam pressure is more common than is generally supposed. Sterilizers made to the 1966 edition of B.S.3970, Part 4 (18) do not require a separate steam supply: for further details see Appendix 1. A sterilizer conforming with B.S.3421 (14) does not require steam.

7.13 The design of the steam supply pipework should be checked to ensure that it is capable of meeting the maximum steam demand for short periods with a fall in pressure not exceeding 10 per cent before the final reducing valve. The effect of nearby connected equipment, e.g. laundry equipment, on the steam demand and steam pressure should be carefully considered.

7.14 A connection must be provided on the steam supply line adjacent to the sterilizer to enable steam to be sampled for the presence of non-condensable gases.

7.15 The steam supply to sterilizers should terminate in the plant room in a header which should be adequately vented and trapped. The vent should be a separate item having a cooling pot; it should be installed on the manifold, upstream of any steam supply to individual

sterilizers. The header should be of generous proportions, e.g. for an installation comprising two 21 cu. ft. sterilizers a 150 mm. nominal base header running the entire length of the plant room, i.e. about 14 ft., has proved successful.

7.16 It is usually impracticable in the Health Service to generate steam of the requisite dryness, pressure and peak flow capacity for sterilizing from a high pressure hot water installation.

Steam separator and pressure reducing valve

7.17 The quality of the steam is of vital importance to the performance of any sterilizer. Wet steam is one of the causes of wet loads in porous load sterilizers. Superheated steam cannot be relied upon for sterilization.

7.18 There is no completely reliable method of measuring the dryness fraction of the steam in most sterilizer installations. It is good practice to install a separator of known efficiency upstream of the pressure reducing valve or valves at the sterilizer.

7.19 If the sterilizer is to be located very near a boiler or high pressure main it may be necessary to take special steps to prevent super-heating of the steam arising from the pressure reduction. Advice on a general solution cannot at present be given, but guidance can be obtained either from the Directorate of Works Operations or from the Supply Division of the Department.

7.20 The manufacturer is responsible for supplying the separator (where required) and pressure reducing valve for the machine. Pressure reducing valves for sterilizers need very careful selection. The advice of the sterilizer maker and Sterilizing Engineer should be sought before any new type pressure reducing valve is fitted to an existing sterilizer.

Safety valves

7.21 Careful attention must be paid to the location of all safety valves to ensure that effective protection is afforded to both chamber and jacket, regardless of the closure of any associated control valve. The safety valve(s) and discharge pipe(s) should be of a size sufficient to prevent an increase in pressure of more than 10 per cent in the chamber and jacket. Any rising discharge pipe must be fitted with a drain at the lowest point. The discharge pipe must terminate in a safe visible position not affected by frost. Any external discharge should be provided with a *tell tale* terminating inside the plant room.

Water supply

7.22 An adequate supply of mains water is required; it is not necessary for this to be purified or sterile. On all new installations the supply must be taken to one or more *break tanks* on the sterilizer, to prevent back siphonage, and not directly to any other component. These break tanks will usually have a ball valve inlet, in which case the minimum air gap between the bottom of the valve inlet pipe and the water level must be (a) not less than 45 mm. for tanks up to 4600 litres capacity and (b) not less than 75 mm. for tanks exceeding that capacity. The overflow must be twice the inlet diameter or 32 mm. diameter whichever is the greater, and the highest level of the water must be not less than 25 mm. below the bottom of the overflow. The distance between the bottom of the valve inlet pipe and the bottom of the overflow pipe must be not less than the diameter of the overflow pipe (see paragraph 5.15.6 of HTM27, Cold Water Supply: Storage and Mains Distribution) (27). On existing installations the supply required for ejectors, vacuum pumps, condensers and heat exchangers of all types should be taken from a break tank for the machines. All break tanks should be covered, easily cleaned and suitably vented. Automatically operated valves should be of the non-percussive type. On large installations secondary re-circulating water cooling systems should be considered. Groups of sterilizers could be served by a common tank or tanks, provided that appropriate cleaning arrangements can be made.

7.23 For optimum performance the water supplied to water ring pumps, condensers and heat exchangers should be at a temperature below 15°C. The performance of these items will also deteriorate if the water is very hard or contains large quantities of solids in suspension; this problem can be overcome by the installation of simple water treatment plant at the sterilizer site.

Compressed air supply

7.24 A compressed air supply may be required. A pressure gauge should be fitted on the compressed air supply main in the plant room. If a mains supply is used the manufacturer must provide any dryer, oil eliminator and filter required for the sterilizer (see 6.37).

Steam or air supplies for door seals

7.25 Where a sterilizer incorporates a door seal which is either pneumatically-operated or steam-operated, the pressure required is in excess of the chamber pressure and, for practical purposes, is of the order of 3·4 bar (50 psig). A suitable supply for door seal service should be provided. This service must be protected by a separate safety valve.

Drainage

7.26 Condensate from the chamber may be contaminated and unsuitable for recovery, and it must pass via a clear air break into a tundish or tank which should discharge by gravity into a suitable trapped foul drain of adequate size and capacity (except as in 7.27). The air break in the tundish or tank must be preserved at all times, so that the sterilizer and its associated piping cannot be contaminated by the foul drainage system (i.e. the discharge rate from the tundish under all working conditions should be such that the maximum flow rate

of effluent from the sterilizer will not cause the water level in the tundish to rise sufficiently to reach the outlet end of the sterilizer effluent pipe, thus eliminating the air break). Where a tank supplies water to a water ring vacuum pump or a water pump used for a water ejector vacuum system, the overflow discharge from the tank must include an air break.

7.27 The advice of the consultant microbiologist (see 2.2) should be sought where a bacteriological hazard is likely to arise. A sealed break tank in lieu of a tundish may be required for each sterilizer. This should be vented to the outside of the building and the vent should terminate above roof level clear of any ventilation inlet, window, etc. A trap should be provided between the break tank and connection to the drainage system. These arrangements will be required where the sterilizer is to be used for processing bacteriologically hazardous material which has to be made safe, e.g. in certain laboratory applications. STERILIZERS USED IN THE PRODUCTION OF STERILE PRODUCTS FOR EITHER PHARMACEUTICAL OR CLINICAL USE SHOULD NOT EMPLOY THIS TYPE OF DRAINAGE SYSTEM. The consultant microbiologist must be consulted on this subject about all sterilizers for any High Security Infectious Diseases Unit.

7.28 Condensate from the jacket, steam separator and other trapping points on the steam pipework may be recovered when it is convenient and economic to do this.

7.29 Means should be provided to prevent, as far as possible, flash steam being liberated into the atmosphere or causing condensation on electrical items. (Tundishes should be appropriately shaped and sited.) The use of plastic drainage pipework may be inappropriate because of the discharge of hot water.

Pipework arrangements

7.30 All steam pipework must be designed so that any condensate flows by gravity in the same direction as the steam. This general principle applies equally to steam mains, branch connections and pipework on the sterilizer itself. Care should be taken to trap and drain any condensate which may be collected in pockets in the pipework or the sterilizers. Deadlegs should be avoided.

7.31 Care should be taken to ensure that sterilizers are connected to mains services which are of adequate capacity and otherwise suitable for the sterilizer load requirements. Inadequate services may cause malfunctioning; for example, compressed air operated valves or door seals may fail if the pressure fluctuates.

Commissioning procedure

7.32 Sterilizers should be commissioned on site, using the principles set out in HTM No. 17, Health Building Engineering Installations: Commissioning and Associated Activities (28). The process of setting sterilizers into full working order should be undertaken by the Contractor in accordance with the instructions set out in the contract documents. It will be necessary for him to provide the test instruments and equipment and to perform the tests and demonstrations which are required before the installation can be accepted for use in accordance with the contract, to the satisfaction of the Contract Supervising Officer (CSO), or someone appointed by him to act on his behalf in this matter. The hospital will provide the load. The various checks and tests are referred to in Appendix 5 and summarized in Appendix 6. The most important individual tests are described in detail in other Appendices. The Sterilizer Engineer should be nominated either as the CSO or nominated to act on his behalf.

7.33 The Contractor must satisfy the CSO that the accuracy and condition of his instruments and equipment meet the requirements for test instruments specified in Appendix 2, paragraph A2.33 *et seq.* and that they have been calibrated on site as described therein.

7.34 Commissioning is a serial process in which work is completed on site in the following order by the Contractor or Contractors:

a. demonstrate the adequacy of *services*;

b. demonstrate the general *engineering* performance of the sterilizer;

c. test the mechanical and electrical function of the sterilizer, including safety devices;

d. test the specific sterilizing performance for the class of sterilizer (see Appendices 7–13).

These procedures should be witnessed by the Sterilizer Engineer. Some guidance on procedures b. and c. is given in Appendix 5 but it is not exhaustive and does not cover every case. The Contractor will not be responsible, unless otherwise specified, for tests to establish Master Temperature Records (MTRs) for production control purposes.

7.35 On satisfactory completion of the work as in 7.34 the Sterilizer Engineer should carry out further tests on the sterilizers, as necessary, to obtain initial performance data for the use of the Maintenance Engineer and the User. He should also establish MTRs for sterilizers processing medicinal products and for hot air sterilizers.

7.36 Arrangements should be made to ensure that all staff concerned with the operation and maintenance of the sterilizer have ready access to manufacturers' instructions, service manuals and the data recorded during commissioning. Maintenance and operating procedure is covered extensively in Appendix 4. The importance and subsequent use of the records taken during commissioning is also referred to in Appendix 4.

8 The testing of sterilizers

Normal test procedures

8.1 The instruments required for testing sterilizers are described in Appendix 2. The frequencies at which tests should be undertaken routinely are set out in the table of Sterilizer Performance Tests in Appendix 6.

8.2 In addition, tests will be required following certain maintenance work which may be either scheduled or unscheduled, as described in the notes accompanying the table in Appendix 6.

8.3 The tests are as follows:

a. performance tests for porous load sterilizers—see Appendix 7;

b. Bowie/Dick tape test for porous load sterilizers—see Appendix 8;

c. leak rate test for porous load sterilizers—see Appendix 9;

d. air detector performance test for porous load sterilizers—see Appendix 10;

e. performance tests for fluids sterilizers—see Appendix 11;

f. performance tests for unwrapped instruments and utensils sterilizers—see Appendix 12;

g. performance tests for hot air sterilizers—see Appendix 13.

Non-standard test procedures

8.4 The use of spore tests or chemical test devices (other than the Bowie/Dick tape test for porous load sterilizers) for routine testing of positive pressure steam sterilizers and hot air sterilizers is not recommended. Where the attainment of sterilizing conditions cannot be confirmed by measurement of physical parameters, the advice of the responsible microbiologist should be sought in evaluating a sterilizing process (see paragraph 12.82, Guide to GPMP) (2).

9 Procedure for dealing with defective sterilizers and reporting accidents

General

9.1 No attempt should be made to open a chamber door under FAULT conditions by defeating the door interlock unless:

a. the chamber is at atmospheric pressure;

b. any fluids in rigid containers are at a temperature below 80°C.

In the case of b. the bottles should be allowed to cool naturally overnight.

9.2 Reference should be made to Appendix 4, which sets out the responsibilities of the various parties involved and includes sections on fault procedures, on recording of faults and on the Plant History Record.

Reporting defects

9.3 The importance of prompt reporting and recording of all faults or abnormalities is emphasized. When complaints about performance have arisen, it has often been found that known faults have not been recorded and reported to the Maintenance Engineer. Failure to report and/or withdraw machines from service following difficulty or abnormality affecting doors or their closing and locking mechanisms has resulted in serious accidents (29).

Reporting and recording accidents

9.4 Accidents in which anyone is injured or could have been injured are reportable under the Health and Safety at Work Act 1974 (6) and must be recorded in the Accident Record Book.

Reporting explosions

9.5 Whether or not anyone is injured, any explosion of a sterilizer or associated steam generator, e.g. bursting of any part of the chamber, jacket, door or vessel or bursting open of the door whilst under pressure, is a "boiler explosion" for statutory purposes. The procedures specified by the Department must be instituted forthwith in the event of any such explosion. Attention is drawn to the following:

a. the requirement to notify both the Directorate of Works Operations and the Supply Division of the DHSS and equivalent bodies in Scotland, Wales and Northern Ireland as well as the local Health and Safety Inspector;

b. the requirement not to disturb the scene of the accident pending examination by the Health and Safety Inspector, and by DHSS officers if they so wish. In particular no part of the sterilizer or steam generator should be touched except in so far as is necessary to make it safe pending investigation, e.g. to isolate services to it.

Reporting to DHSS

9.6 Attention is drawn to the provisions for reporting accidents, defects and failures to DHSS, etc., so that action may be taken with manufacturers if appropriate, and in order that other NHS users may be warned about potential hazards. Reports should be made both to the Supply Division and Directorate of Works Operations of the DHSS, as indicated in HSC(IS)41 (30) (under revision); see also "Hospital Service Engineering", No. 30, page 18 (31). The types of occurrence which should be reported are those where some central action may be helpful in bringing about necessary improvements in the standards of safety, construction, performance, reliability or economics of sterilizers and would include for example:

a. accidents involving sterilizers;

b. failures of the integrity of the pressure vessel, i.e. failures of door mechanisms, explosions and bursting or cracking of parts of the chamber, door, jacket or structural members;

c. incipient or potential defects likely to lead to failures as at b. above;

d. failures of the basic safety devices connected with closing/opening of the door and pressurization of the chamber;

e. failures of electrical safety;

f. any constructional features which do not comply with safety codes or with accepted good practice or are hazardous in some way;

g. any unusual circumstances which may jeopardize safety or proper functioning, e.g. if safety devices or the automatic process controls can be defeated under certain conditions;

h. inability of a properly maintained and operated machine to meet the performance standards specified for it;

j. unreliability, persistent malfunction, frequent failures of particular components or any other feature which generates excessive and/or abnormally expensive maintenance or operational requirements, having regard to the intensity of use and operating conditions.

10 Maintenance and operation policy and procedure

General

10.1 The importance of adequate maintenance was emphasized in paragraph 12 of the Report referred to in paragraph 2.1, and this was reinforced by paragraph 6 of HM(67)13 (4) which stated that planned maintenance arrangements should be made for sterilizers as soon as possible. Arrangements for proper maintenance of all sterilizing equipment should be made by Area Health Authorities with advice and assistance, where necessary, from Regional Health Authorities. The maintenance and testing of sterilizers are specialized functions.

10.2 Reference should be made to Appendix 4 which sets out the responsibilities and procedures involved and emphasizes the need for close co-operation between the Sterilizer Engineer, the Maintenance Engineer and the User.

10.3 The Sterilizer Engineer should have the necessary testing facilities to monitor sterilizer performance by fully instrumented tests; the Maintenance Engineer needs less sophisticated equipment.

10.4 Attention is drawn to the advice and assistance available from the following sources:

a. Manufacturers.

b. Directorate of Works Operations DHSS Branch 3.1.2.

c. Supply Division DHSS, Scientific and Technical Services Branch (STB 4A).

d. The appropriate authorities in Scotland, Wales and Northern Ireland.

Maintenance and testing philosophy

10.5 The philosophy on maintenance and testing embodies three main principles to ensure that adequate standards of performance and safety are attained and sustained. These are as follows:

a. that all sterilizers are subjected to a carefully planned programme of tests to monitor their performance (see Appendix 6);

b. that all sterilizers are subjected to a programme of planned preventive maintenance (PPM) under the control of the Maintenance Engineer, *irrespective of whether or not a planned preventive maintenance scheme is being operated in the hospital generally*;

c. that expertise on all aspects of the engineering management of sterilizers should be available at two levels; these are operated by the Maintenance Engineer and the Sterilizer Engineer.

10.6 The scheduled test programme includes simple testing methods undertaken by the user, as well as the

more complicated tests undertaken either by the Maintenance Engineer or by the Sterilizer Engineer. The test programme fulfils the objectives set out in Appendix 4 by demonstrating whether or not the equipment is functioning satisfactorily.

10.7 The scheduled tasks in the 1978 amendment to the sterilizer sections of Maintenance Manuals PMG/12 (10) and PMG/13 (11) are based on the philosophy set out below. The same basic philosophy should be applied when schedules of maintenance tasks are being prepared to suit local circumstances. The philosophy has the following requirements:

a. All parts of the sterilizer which are vital to correct functioning and/or safety must be tested at least weekly. This is interpreted thus:

(i) there is no need to test components individually in those cases where any malfunction will be revealed by the sterilizer performance tests prescribed for weekly or more frequent intervals; and

(ii) where correct functioning of particularly important components is not necessarily verified by the performance tests prescribed for the sterilizer at least weekly, those components must be individually tested each week and reference to testing them must be included in the schedules of maintenance tasks. This applies, for example, to some door interlocks which may only be required to perform their safety function when presented with an abnormal condition.

b. The maintenance routines should include those tasks such as lubrication and occasional dismantling of particular components, e.g. pumps, the need for which, at appropriate intervals, is indicated by normal good practice, manufacturer's advice and experience. Apart from those tasks, the maintenance routines should concentrate on verifying the condition of the sterilizer and its components by means of testing and examination without dismantling, e.g. parts which are working well should be left alone and not disturbed unnecessarily.

Plant History Record and Sterilizer Processing Log

10.8 Appendix 4 (paragraph A 4.25 *et seq.*) indicates that a Plant History Record must be kept for every sterilizer and that a Processing Log must also be kept for sterilizers processing medicinal substances and for porous load sterilizers.

Routine cleaning and preparation

10.9 The operational duties to be carried out by the User (or by the Plant Operator under the User's supervision) should be recorded in a written form, and the procedures include those mentioned below.

a. It will not usually be necessary to clean the chambers of porous load sterilizers daily, but each day the interior of the chamber of other machines, including trays and shelves, should be wiped down with a clean damp cloth. Cleaning is especially important for fluids sterilizers dealing with saline solutions. The use of abrasives or cleaning materials which leave deposits must be avoided. A mild detergent may sometimes be used, followed by a clean water rinse. A detergent cleaning procedure must not be adopted on fluids sterilizers which use rapid coolers of the "condensate-collecting" type. On such machines the chamber, etc., should be wiped down and cleaned in accordance with the manufacturer's instructions. In those cases where it is impractical for this to be done by the User, it should be done by the staff of the Maintenance Engineer.

b. The grating in the opening to the chamber discharge line should be cleaned daily, or more often if necessary. This can normally be done by the User where it is readily accessible, or otherwise by the Maintenance Engineer's staff.

c. The door seal should be wiped clean each day with a damp cloth and inspected for damage. This can normally be done by the User if the seal is completely exposed when the door is open, though the inspection will then be a cursory one. Where access is difficult it should be done by the Maintenance Engineer's staff.

d. Attention must be paid to the requirements that certain instrument readings are to be recorded at the commencement of the day (see Appendix 4, paragraph A 4.48). Any deviation from normal should be reported and investigated before work proceeds.

e. On many fluids sterilizers fitted with rapid cooling, the chamber condensate is collected for use as the coolant; if a container fails the contents will therefore flow into the coolant pipework and tank. The condensate should be dumped at the end of each cycle. If it is not dumped, some solutions, particularly saline, may cause serious damage to the sterilizer. For this reason the cooling system of such machines should be flushed after such leakage has occurred; the system should in any case be flushed periodically (usually weekly) as part of the PPM routines carried out by the Maintenance Engineer. For this purpose it may, in some cases, be necessary to open a drain plug in the storage tank.

Temperature recorders and record charts

10.10 A temperature recorder should be treated as a valuable instrument to monitor the general functioning and performance of a sterilizer. Temperatures read from a recorder should, however, be regarded with caution and interpreted only in the light of previous records and tests, and knowledge of the characteristics of the particular sterilizer/load/recorder combination and the position from which the recorder senses. Temperature sensing and measuring instruments (especially recorders) are subject both to inherent

calibration errors and to loss of calibration with use. No batch of sterile fluids or load processed by a hot air sterilizer should be passed as sterile unless the Temperature Recorder Chart (TRC) is satisfactory when compared with the corresponding MTR, and any abnormal trace should be reported to the Maintenance Engineer.

10.11 A recorder should not be interfered with more than is absolutely necessary whilst it is working correctly. The manufacturer's instructions on operation and adjustment must be strictly adhered to. Maintenance of these instruments demands specialized attention and is best undertaken by the manufacturer.

10.12 All persons who may need to change charts and/or replenish ink supplies on recorders during the course of their duties should be properly instructed, so that they appreciate the delicate nature of these instruments, and effectively trained in the performance of these duties. Only persons who have received such instruction and training and who are accepted as suitably competent by the Sterilizer Engineer or Maintenance Engineer and by the User should be permitted to change charts and replenish ink.

10.13 The instrument case should never be left open; broken glass should be replaced promptly.

10.14 The preparation and use of MTRs and TRCs and the vital role these play in the management and control of sterile material production is set out in Appendix 4. The special importance of recorder charts in the quality assurance documentation associated with the production of sterile aqueous fluids and other medicinal substances is also described in the Guide to Good Pharmaceutical Manufacturing Practice (2).

Maintenance—staff and training

10.15 It is most important that staff at all levels whose duties include responsibilities for the maintenance of sterilizers have a sound general knowledge of the principles, design and functions of sterilizers. They must be thoroughly instructed and familiar with those types and models of machine with which they are directly concerned. They should have some knowledge of the basic elements of microbiology in order to ensure personal safety, the safety of others and general safety. In particular the Maintenance Engineer should be fully conversant with all the machines for which he is responsible. There will usually be some routine tasks which have to be done by NHS staff, even if maintenance is normally carried out under contract. In addition, the Maintenance Engineer must be in a position to be able to deal with any breakdown in an emergency. He should also have the ability to diagnose faults and carry out repairs or to arrange for repairs to be carried out by his staff. He must be competent to supervise and monitor work carried out either by NHS staff or under contract, and to conduct quarterly and half-yearly tests (see Appendix 6).

10.16 Various courses suitable respectively for senior engineering management, for engineers with direct responsibility for maintenance and for engineering tradesmen are run at Falfield. These courses may also be of benefit to "Users".

10.17 Detailed instruction about particular sterilizer models is usually best obtained from the manufacturers, either on site, e.g. during commissioning, or by courses at their works.

Planned preventive maintenance (PPM)

10.18 A suitable system of planned preventive engineering maintenance is described in ESTMANCODE (8). This is a well-tried, tested and recommended system (previously published as Hospital Technical Memorandum No. 13 (9) which has been widely used in the NHS for many years).

10.19 The PPM programme supplied by the manufacturers should be used for all new sterilizers (see 6.10). For existing sterilizers the manufacturer's recommended PPM programme should be used wherever it is available. In the case of an existing sterilizer for which no manufacturer's programme can be obtained, a programme based on PMG/12 and PMG/13 should be drawn up jointly by the Sterilizer Engineer and the Maintenance Engineer.

10.20 ESTMANCODE emphasizes the need to review PPM programmes regularly and to adjust their content and frequencies in the light of experience and local conditions. The schedules of maintenance tasks in PMG/12 and PMG/13 are, necessarily, typical and provide a basic guide; the various points included will not all apply in every case, neither will they necessarily be comprehensive. The schedules must be adapted, after taking manufacturer's advice wherever possible, to suit each particular sterilizer and the prevailing conditions. The PPM frequencies embodied in the PMG/12 and PMG/13 schedules, and in most manufacturers' schedules, are based on an average intensity of use, typically that of a sterilizer in a CSSD or TSSU working on a normal single shift basis. If the intensity of use differs significantly from that, some of the frequencies may need to be adjusted accordingly; in any case, frequencies should be kept under review in the light of operational experience. It is important to ensure that sterilizer maintenance work is pre-planned as much as possible to fit in with production schedules.

10.21 Although the manufacturer is required to carry out certain inspection and maintenance procedures under the terms of his guarantee, it is essential that engineering staff undertake the PPM programme at all times, including the guarantee period, unless otherwise stipulated in the contract (see 6.13). The Maintenance Engineer must also implement any further reasonable instructions given by the manufacturer during the period of the guarantee. Failure to do this may involve the manufacturer in additional expense for which he

may seek reimbursement and it might also jeopardize the protection afforded by the manufacturer's guarantee.

10.22 Before commencing the Weekly Tasks the Maintenance Engineer should satisfy himself that the Daily Tasks have been carried out by the User or Plant Operator on the lines indicated in paragraph 10.9, that any approved routine tests, e.g. the Bowie/Dick tape test, have been carried out and the results properly recorded by the User. If he is not satisfied he should record his dissatisfaction in detail in the Sterilizer Processing Log, or in the Plant History Record where a Processing Log is not required, and draw the attention of the User to the matter.

Overhauls

10.23 The Maintenance Engineer should arrange for each sterilizer to receive a thorough overhaul every two years. This should be arranged to coincide with the statutory inspection by the insurance company's Engineer Surveyor. The overhauls and inspections should be staggered in the maintenance programme so that in any particular installation only one machine at a time need be withdrawn from service. Arrangements should be made for assistance from another department and/or for overtime working if the need for standby capacity arises during normal overhauls.

Calibration of instruments fitted to the sterilizer

10.24 Every three months, or more frequently if considered necessary, the accuracy of the gauges and thermometers should be ascertained by the Maintenance Engineer. Any instrument which is found to read seriously in error or which is inconsistent, i.e. will not repeat satisfactorily, must be discarded, or repaired by the makers if that is practical and economic. Instruments which do repeat satisfactorily but read slightly in error should be dealt with as follows:

a. instruments fitted with pointer adjustment facility should be adjusted to read correctly at the normal working temperature or pressure;

b. if the instrument has no provision for pointer adjustment it should be replaced as soon as possible by the Maintenance Engineer and the User should be advised accordingly.

Air-tightness of the chamber

10.25 Air-tightness of the chamber is of fundamental importance to the correct functioning of all sterilizers. The effectiveness of the door seal is the chief factor in the air-tightness of the chamber as a whole and it must receive particularly careful attention as advised by the manufacturer. The working life of door seals varies widely, but it is essential that all seals are renewed regularly at the intervals recommended by the manufacturers. Seals must also be renewed when there is any evidence of damage or deterioration.

10.26 Although the door seal is the major potential source of air leakage into the chamber, there are many other points at which leakage is liable to occur; these include joints in pipework, connections to gauges, blanked off connections for test gauges, thermocouple entry points (both when in use and when blanked off) glands or seats of various valves and door safety interlocks. Pipework joints and connections to the chamber sometimes develop leaks after a period in service, probably due to slight loosening caused by the repeated stress reversals associated with alternating pressure and vacuum conditions, especially where compression fittings have been used. Occasionally air leakage into the chamber may be the first recognized symptom of cracks developing in the chamber welds or platework.

Air detection devices on porous load sterilizers

10.27 A leak in an air detection device might be so small that it would be unnoticed by the ordinary leak rate test, but such a small leak would have a very serious effect in most machines since it would permit the expulsion by steam of any air present in the device. This would indicate falsely that all air had been removed from the chamber. With certain designs of air detector the converse may also be true and a leak may cause the air detector to reject every load.

10.28 Particular care must be taken when installing, removing or adjusting any part of this device. It is preferable not to interfere with it except when necessary. The routine procedure to be adopted for determining the sensitivity of the detector is normally as stated by the manufacturer (see also Appendix 10).

Stainless steel chambers

10.29 Stainless steel is used in the manufacture of many chambers and these may be of solid stainless steel or of stainless steel clad mild steel. Over a wide variation in specification, stainless steels are susceptible to crevice corrosion and stress corrosion cracking, initiated by chemical attack. These phenomena occur when the material is subjected to a combination of stress, heat and contact with chemicals, notably chlorides or strong alkalis. Damage is likely to occur when these factors are acting together, even though they are at levels far below anything which would be of significance taken separately. The first two factors, stress and heat, are necessarily present in all steam sterilizers. The third factor, chemical contact, may also be present in sterilizers under the following circumstances:

a. in sterilizers processing certain fluids, a spillage, e.g. by the breakage of a bottle of saline solution, will introduce chloride salts into the chamber;

b. in small electrically heated sterilizers where steam is generated within the chamber by an immersion heater, a build-up of both alkalis and chloride salts may occur if these machines are supplied with tap water:

c. if there is excessive *carry over* of boiler water with the steam, this is likely to include significant concentrations of both alkalis and chloride salts;

d. in addition to the risks of stress corrosion cracking, cases have occurred in certain parts of the country where the use of tap water in electrically heated bench top sterilizers has resulted in severe pitting corrosion leading to perforation of the chamber (see paragraph 3.7).

Both crevice corrosion and stress corrosion cracking can largely be prevented by correct operational procedures together, where appropriate, with regular cleaning and light hand polishing of the chamber to remove microscopic initiating sites. It is particularly important to ensure that the stainless steel chambers of fluids sterilizers are polished at quarterly intervals, and that the cooling systems are flushed as required in 10.9e. Manual use of iron free abrasives should be employed for polishing. Conventional engineering abrasives such as emery and carborundum may be used. Household or domestic scouring and polishing compounds must not be used since they often contain chlorine or other corrosive agents and might thus cause, rather than prevent, trouble. The manufacturer's advice should be followed and care taken not to damage the door seal. Precautions must be taken to prevent the entry of foreign matter into the chamber drain during polishing and cleaning; the drain should be disconnected while the work is in progress and the chamber should be thoroughly flushed out before the drain is re-connected.

Note: THIS CLEANING TREATMENT IS NOT NECESSARY ON NICKEL CLAD STEEL CHAMBERS.

Maintenance of ancillary equipment

10.30 Because of the wide variation in design of devices performing similar duties, manufacturers' instructions should be consulted about maintenance and operation of these items.

10.31 Where sterilizers incorporate standard items such as air compressors, air receivers or water softeners, the schedules of maintenance tasks in the relevant sections of PMG/12 and PMG/13 will be applicable.

Steam generators

10.32 Local steam generators, whether provided separately or as an integral part of a sterilizer, are steam boilers and they must be recognized and treated as such. Although they are equipped for automatic operation they must receive regular supervision such as would be accorded any other automatic steam boiler plant. It is not acceptable for them to be left unattended for more than 24 hours; they must be looked at by a competent boiler attendant or engineer at least daily whilst in use and in many cases more frequently. They are notoriously liable to trouble from scale formation.

10.33 The amount and frequency of attention necessary in each case will depend largely on the nature of the water supply, water treatment arrangements and the intensity of use. Because there is often little or no condensate returned to these steam generators, their feedwater is usually almost 100 per cent "make-up", and as a result the concentrations of dissolved and suspended solids in the boiler water build up quickly to very high levels. It is essential that an effective blowing-down regime be established, and adhered to, in order to contain the dissolved and suspended solids concentrations in the boiler water within acceptable limits. The advice of the manufacturer about water supply, water treatment, blowing-down and other operational practices should be strictly observed (see also Appendix 1).

10.34 Attention to water quality inside the generator is especially important if, as is often the case, the generator vessel is of stainless steel, since this may be subject to the same risk of stress corrosion cracking encountered in stainless steel sterilizer chambers (see paragraph 10.29).

10.35 Failures to provide adequate supervision, with consequential inadequate control of water quality including insufficient blowing-down, have resulted in such severe corrosion of steam generators that in some cases internal parts have collapsed and the safety of operators has been seriously jeopardized.

Return of sterilizers to service after maintenance

10.36 Whenever any maintenance work, either scheduled or unscheduled, has been carried out on a sterilizer, it should not be returned to service until the following requirements have been satisfied:

a. it has passed functional tests appropriate to its type and the particular circumstances (see Appendix 6);

b. both the Maintenance Engineer and the User are satisfied that it is functioning correctly (in the case of machines processing medicinal substances, the "User" should include both the Production Manager and the Quality Controller);

c. in certain circumstances (see Appendix 4, paragraph A4.40, items a. to h.) the Sterilizer Engineer is also satisfied that it is functioning correctly.

10.37 In every case the tests to be applied will include running the machine through a full cycle under automatic control, with a standard load, whilst significant cycle parameters (e.g. temperatures, pressures and times) are logged and checked against the normal values for that machine (see Appendix 4, paragraphs A4.17 and A4.31a). Other tests will also be involved, including approved standard tests such as the Bowie/Dick tape test and the leak rate test, where relevant, and on some occasions fully instrumented tests using multi-channel thermocouple recorders will be required.

11 Hot air sterilizers

Introduction

11.1 Hot air sterilizing is an accepted method for those loads into which steam cannot readily penetrate e.g. assembled syringes, and for non-aqueous products e.g. oils and powders.

11.2 In steam sterilizers, the heating of the contents is effectively achieved by latent heat transfer, whereas hot air sterilizers rely on sensible heat transfer only. Even temperature distribution throughout the chamber and load is essential, and this is best achieved in hot air sterilizers by forced air circulation, i.e. by means of a fan.

11.3 Most existing hot air sterilizers are not equipped with the safety devices and automatic cycle controls usually associated with steam sterilizers, and most are at present manually operated. It is essential, therefore, that their use is controlled by responsible persons who are adequately trained.

11.4 Various combinations of time and temperature are recommended by the Medical Research Council in MRC Memorandum No. 41 (1962) (32). The time/temperature relationships normally used are as follows:

160°C—60 minutes
170°C—40 minutes
180°C—20 minutes

Additionally, for certain pharmaceutical products } 150°C—60 minutes { ref British Pharmacopoeia 1978 (33)

Note: The items to be sterilized must be held at the stated temperature for at least the time given above; heating up and cooling down times are additional.

Recommendation in respect of hot air sterilizers for the National Health Service

11.5 Sterilizers should conform with B.S.3421—Specification for Performance of Electrically Heated Sterilizing Ovens (14).

11.6 A hot air sterilizer is not suitable for use as a drying cabinet—such drying cabinets should conform with B.S.2648 (34).

11.7 A suitable thermocouple entry port should be provided.

11.8 Automatic process control is desirable and should be introduced. All new sterilizers should be automatically controlled.

11.9 The door must be capable of being locked. It is preferable that the locking system be automatic as in paragraphs 11.16 and 11.17, but alternatively a simple key-operated lock for control by the User is acceptable.

Instrumentation and process control

11.10 Instrumentation (which should include a chart recorder and indicating thermometer) required for hot air sterilizers is referred to in Appendix 2. The sensors for the indicating thermometer and the temperature recorder should be permanently fixed. The thermometer and recorder may show different temperatures because the sensing elements may be located separately, but their sensors should be sited in positions which will minimise this difference.

11.11 An overheat cut-out should be fitted to all hot air sterilizers (see 11.15).

11.12 Although fully automatic controls with full stage indication are desirable on all sterilizers, and essential on new sterilizers, where these cannot be provided the following table indicates those features considered either essential or desirable for effective manual control.

Item	*Feature*	*Essential*	*Desirable*
	(A) CONTROLS		
1	Push button or starting switch for the process, separate from mains isolating switch	YES	
2	Manually adjustable process timer (0–6 hours)	YES	
3	Sterilizing temperature control thermostat, adjustable over the range 140–180°C	YES	
4	Overheat cut-out, adjustable up to but not exceeding 200°C, with manual reset facility	YES	
5	Independent adjustable thermostat (0–100°C) to permit fan to continue to run after sterilizing stage until load temperature has fallen to preselected temperature (normally around 60°C)		YES
	(B) STAGE INDICATORS		
6	Electricity supply switched on	YES	
7	Chamber heaters energized	YES	
8	Fan run-on timer operating	YES (if applicable)	
9	Process complete	YES	
10	Fault condition		YES
11	Door release		YES
12	Three digit process counter	YES	

11.13 Adjustment of timers and the sterilizing temperature thermostats should either require the use of

tools or the controls should be protected against inadvertent adjustment; the settings should, however, be visible to the user. The reset button for the chamber over-heat cut-out and the door release over-ride should be similarly protected; alternatively key switches may be used.

Safety features required

11.14 All controls should be designed to fail safe wherever practicable.

11.15 A manually re-settable, non-self re-setting overheat cut-out, set to operate at a temperature not exceeding 200°C, should be fitted to all hot air sterilizers.

11.16 The door should be interlocked so that the operating cycle can neither be started until it is closed and secured nor opened until a satisfactory sterilizing cycle has been completed, except by the use of a manual over-ride release not normally accessible to the operator.

11.17 A sterilizer with doors at opposite ends should have interlocks to ensure that both doors cannot be opened together, and the door at the "unloading" end can be opened only after the completion of a satisfactory sterilizing cycle.

11.18 If the electricity supply is interrupted before a cycle is completed the process timer should automatically reset to zero and require manual reset. Restoration of the electrical supply should be signalled by the fault indicator, but there should be no automatic re-starting of the process.

The use of hot air sterilizers

11.19 Users must ensure that the selected process time is that stated on the MTR as defined in Appendices 13 and 14. In addition, the batch type and size, loading pattern and shelving system must be in accordance with the information stated on the MTR.

11.20 The process time is the sum of:

a. the time taken for the free chamber space to achieve temperature;

b. the time required for all parts of the load to reach temperature;

c. the sterilizing time.

Note: If a separate cooling thermostat is fitted the total cycle time will be longer, i.e. the processing time plus cooling time.

11.21 Variation from the established loading pattern may seriously affect the heat distribution in the chamber and sterilization may therefore not be achieved throughout the load.

11.22 Consideration should be given to the provision of either purpose-made shelving, or spacers, for accurate and repeatable positioning of specific load items, so that the loading pattern used for the preparation of the MTR is repeated in production loads.

11.23 The chamber should not be over-filled.

11.24 Good thermal contact is desirable between load items and their containers. In the case of particularly heavy instruments, it is desirable to support the instrument by a metal cradle within its container to assist heat transference by conduction and thus avoid an excessively long time for the whole load to reach sterilizing temperature.

11.25 Improved heat transfer can be obtained by wrapping the items in aluminium foil. This may be preferable to wrapping them in paper, or enclosing them in glass tubes or metal containers.

Appendix 1

Steam quality, wet loads and superheating

General

A1.1 This Appendix applies mainly to steam supplies for porous load sterilizers and sterilizers for instruments and utensils.

A1.2 The pre-requisite for efficient steam sterilizer performance is a steam supply of suitable quality. Problems are unlikely to occur if the dryness fraction is approximately 0·9 before the final reducing valve and the pressure reduction ratio through the valve is of the order of 2 : 1.

A1.3 Although experience has shown that acceptable conditions are sometimes achieved when optimum conditions do not prevail, significant deviations are likely to cause the following problems:

a. wet loads, resulting from too low dryness fraction;

b. difficulties with reducing valve operation, resulting from too low pressure reduction ratio;

c. superheating, resulting from either too high dryness fraction before the reducing valve, or excessive pressure reduction through the valve: superheating may be severe if both conditions are present simultaneously.

A1.4 The steam supply to the reducing valve on the sterilizer should not be subjected to pressure fluctuations in excess of 10 per cent.

A1.5 Adequate trapping and venting of the steam supply system, good installation practice to remove condensate, air and non-condensable gases, and efficient thermal insulation are important if problems arising from poor steam quality are to be avoided.

A1.6 When existing sterilizing equipment is to be replaced, it is desirable to appraise the steam supply system, because the dryness fraction of the existing supply may not be appropriate for the proposed new equipment.

A1.7 Superheating of steam in the chamber may be avoided by using two or more stages of pressure reduction. The reducing valves should be installed some distance apart, so that the normal heat losses from the pipe will sufficiently reduce the energy of the steam, and expansion through each valve will not result in superheating.

Wet loads

A1.8 This section is directed almost entirely to problems arising with porous load sterilizers and with sterilizers for unwrapped instruments and utensils.

A1.9 Although wet steam supplies will usually result in wet loads, experience has shown that a high proportion of wet load problems can be attributed to improper wrapping or packing of the load and improper loading of the sterilizer, particularly when metal or other heavy objects are being processed in a porous load machine.

A1.10 The energy which heats the load is derived almost entirely from the latent heat given up as steam condenses. The greater the mass of the individual objects in the load, the greater is the amount of steam condensed during this heating process and the greater is the energy absorbed by each object. The process is substantially reversible. By subjecting the chamber to a vacuum during the drying stage, the lowered boiling point of water associated with the reduced pressure enables the heat energy stored in the object to be used to re-evaporate the condensate, and as a consequence the object is cooled. It is evident that the re-evaporation process will not occur if the condensate becomes separated from the object to which the latent heat has been imparted. In order to ensure dry loads it is necessary either to retain the condensate close to the object on which it was formed during heating or to ensure that the condensate is drained clear of the load. Parts of the wrapping are likely to become saturated in certain cases. This saturation may occur at an early stage of the heating process when objects such as metal instruments having a relatively high thermal mass are sterilized. The excess condensate in these cases may migrate to other parts of the load from which it may not be evaporated; it is likely to be a particular problem when the objects are heavy. This migration of condensate may be avoided by including ABSORBENT material, suitably positioned inside each pack and quite separate from the wrapping. The optimum amount and arrangement of this extra padding can only be determined by experiment.

A1.11 As far as possible, loads should be arranged so that condensate runs directly to the drain, away from the individual objects, e.g. holloware should not be processed in an upright position (holloware must in any case be inverted in unwrapped bowl and instrument sterilizers so that air will be displaced). In porous load sterilizers it may not be practicable to ensure that wrapped holloware is always processed inverted, but the drainage problem may then be overcome by placing absorbent material inside the vessels.

A1.12 Wet patches on loads may also result from condensate dripping or draining on to the load from load containers or from loading carriages of poor design. They may also result from processing tiers of instrument trays without using drip deflectors between each tier.

A1.13 The advice of the Sterilizer Engineer should be obtained when all normal procedures fail to secure dry loads.

Appendix 1 continued

Wet steam supply

A1.14 Some wet loads are undoubtedly due to the supply of wet steam to the sterilizer. The undermentioned are some of the causes and remedies for this situation.

a. Existing or new steam mains or manifolds which are inadequately sloped and drained. The remedy is obvious.

b. Defective and/or inefficient thermal insulation of the pipework between the boiler and the sterilizer will cause excessive condensation of the supply steam. Effective lagging is essential.

c. There must be a properly designed and correctly installed separator and steam trap set adjacent to the sterilizer.

d. The sterilizer should be connected to a live steam main, not to an inadequately drained or inadequately vented "dead-leg". Long branch connections to sterilizers should be avoided.

e. The steam supply pipework between the mains connection and final separator should fall towards the separator, for drainage into the trap. Additional drain points and traps may be required, depending upon the piping arrangement. The accumulation of condensate in the periods when the sterilizer is not in operation should be avoided, particularly in any part of the pipework and fittings between the take-off from the steam main and the sterilizer chamber. This can be achieved by the correct inclination of each portion of pipework and by adequate trapping.

f. The steam supply to the sterilizer should be taken from the top of the main pipe.

g. "Priming" may be occurring in the boilers. Modern compact and highly rated boilers are particularly sensitive to feed water treatment and are much more likely to prime than boilers of traditional design. Priming or foaming, which results in carry-over of the boiler water, may be caused by:

(i) incorrect feed water treatment (see A1.18 and A1.19 below);

(ii) forcing a boiler which needs internal cleaning;

(iii) violent boiling, under fluctuating load conditions (especially with high water levels).

Non-condensable gases

A1.15 The presence of non-condensable gases in steam mains supplying sterilizers may cause the sterilizer air detector to abort cycles when a leak rate test can otherwise be satisfactorily performed. The presence of these gases may also be revealed by the Bowie/Dick tape test (the setting of the air detector should NOT be modified to compensate for this).

A1.16 Some causes of the presence of non-condensable gases in the steam supply are as follows:

a. boiler feed water which is not properly de-gassed or is allowed to fall below 80°C during periods of high demand (this is often due to general failure to return condensate from the hospital and is sometimes due to inadequate insulation of the condensate return pipe);

NOTE: A simple base exchange system of water treatment does not remove the bicarbonate ions from the water but, in effect, exchanges the scale-forming bicarbonates for sludge-forming bicarbonates which can be removed by blowing down. CO_2 will be liberated during heating, regardless of whether or not this form of treatment is used.

b. inadequate venting and trapping of the steam lines;

c. boiler feed pump glands leaking;

d. incorrect water inlet to feed tanks.

A1.17 Certain boxes or trays, e.g. Bripac boxes when first used, are likely to give off non-condensable gases which will cause the air detector to abort the cycle. Such material should be pre-processed separately before first being used in the normal sterilizing procedure.

Water treatment

A1.18 The quality of the steam may be greatly influenced by the boiler water treatment and a study of the treatment is essential in many cases. The study should cover the analysis of the water, the facilities for venting and the blow-down regime required in order to optimize the total dissolved solids (TDS) content and ensure protection of the boiler against corrosion, whilst minimizing the entrainment of non-condensable gases in the steam supply. This study should be carried out by a water treatment specialist. The use of filming amines is covered by HTM 6—Protection of Condensate Systems (revised 1970) (35), but this form of treatment should be avoided wherever possible since it necessitates careful control and monitoring.

A1.19 It may be necessary to re-assess the water treatment procedure for existing boilers in those cases where the steam quality indicates the need, e.g. where repeated and unaccountable Bowie/Dick tape test failures and/or cycle abortion by the air detector system has occurred. This would certainly be the case when investigation shows that the sterilizer is in good order, but that the steam supply may be suspect.

Small steam generators/boilers

A1.20 Small local boilers and boilers constructed integrally with sterilizers are particularly susceptible to the problems of low boiler feed water temperatures,

inadequate venting and trapping and incorrect water inlet to feed tanks. These problems are accentuated because the condensate from sterilizers is not returned to the feed tank.

Superheated steam

General

A1.21 Superheated steam is an unsuitable medium for moist heat sterilization. (In properly designed sterilizers moist steam at, for example, 134°C will sterilize in three minutes, while dry heat at 160°C will sterilize in one hour.) Superheat conditions within the load and chamber may result from:

a. adiabatic expansion;

b. exothermic reaction;

c. heating from an outside source (e.g. overheated jacket).

Superheating from any cause may result in failure to sterilize, scorching of textiles and paper and rapid deterioration of rubber.

Adiabatic superheating

A1.22 Superheating due to adiabatic expansion is usually the result of an excessive reduction in pressure through a throttling device, e.g. a reducing valve or a partially closed main steam valve. It is unlikely to be of significance in the circumstances normally encountered in hospital steam distribution systems, but it may arise if the main steam supply is unusually dry, or the pressure unusually high before the throttling device.

A1.23 Practical considerations sometimes dictate the need to accept limited adiabatic superheating in the chamber provided it can be demonstrated to be a transient condition. Specifically, the maximum superheat measured in the chamber space must not exceed 5°C and for the last two minutes of the sterilization hold time must not exceed 2°C. Advice may be obtained from the Directorate of Works Operations or from the Supply Division of the DHSS in those cases where these limits are found to have been exceeded.

A1.24 When adiabatic superheating occurs it can sometimes be overcome by installing a second reducing valve in the steam main well upstream of the sterilizer, so that the pressure reduction ratio at the sterilizer is not greater than 2 : 1 thus permitting the heat losses from the pipework to reduce the dryness fraction upstream of the final reducing valve, whilst minimizing the effect of expansion through the reducing valve drying (but if steam is used for door seal inflation the first reducing valve must not reduce the pressure below that required for the seal).

Exothermic superheating[a]

A1.25 Superheating arising from exothermic reaction may occur during sterilizing as a result of re-hydration of exceptionally dry material. In these circumstances the superheat condition is not necessarily transient; it may be severe and may persist for the entire sterilization hold time, with consequential risk of a failure to sterilize. This phenomenon is usually associated with certain textiles, particularly those incorporating cotton, which have become excessively dry before sterilization. It may occur at any time when the ambient humidity is unusually low. It is generally revealed by thermocouple testing but only if the material used for the test pack has been exposed to the same environmental conditions as the production material.

A1.26 It is unlikely to be a problem in most installations during normal UK climatic conditions, but it may occur during the periods of very cold, dry weather, especially in those departments which are heated and mechanically ventilated without humidification. It is also likely to occur in air-conditioned areas if the humidification plant is not functioning properly.

A1.27 Textiles should be allowed a period of not less than four hours for airing after laundering before they are sterilized.

Measurement of dryness fraction

A1.28 Where problems with superheating and/or wet loads cannot be readily overcome, it is desirable to measure dryness fraction in order to quantify the problem. The most successful method involves sampling the steam throughout the air removal stage. The sample should be collected by inserting a capillary probe (pitot) into the centre of the steam pipe (see diagram). The diameter of the probe should be in accordance with the table below.

NOTE: 1. By taking a "core" sample from the steam supply line, a close approximation to chamber conditions is obtained, with the minimum of entrained condensate.

2. A single pan laboratory balance of 1·5 Kg capacity has been found most satisfactory for the accurate weighing that is necessary with this technique.

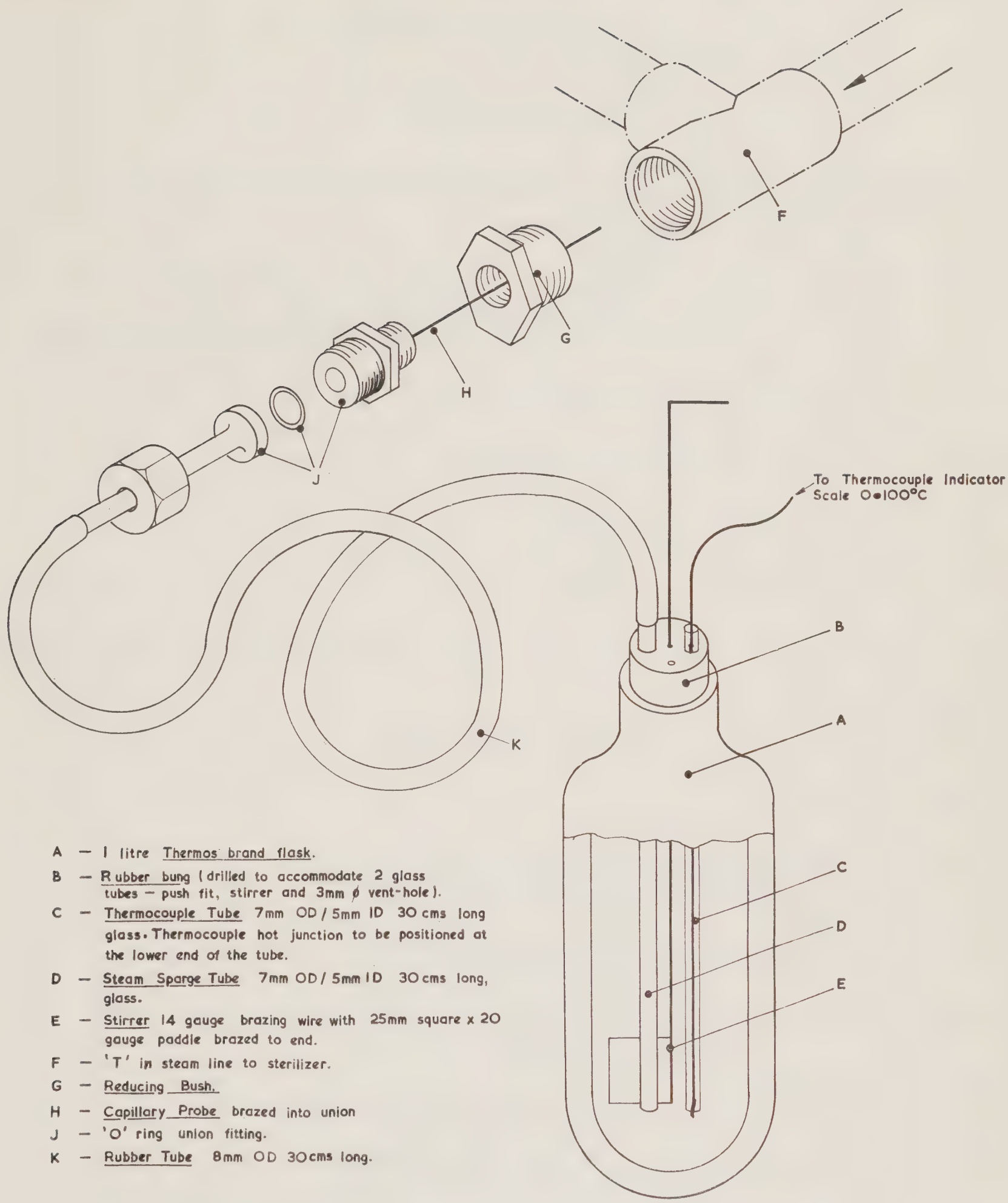
See also "The Efficient Use of Steam" (36).

Method

Steam is injected during the air removal stage into a calorimeter (1-litre thermos flask) which contains a known mass of water at a known temperature. At approximately 80–85°C the steam is cut off by disconnecting the rubber tube so that steam has been sampled during the most active period of steam injection to the sterilizer, i.e. from the commencement of air removal to just after start of sterilizing "hold".

(a) See also Henry, P. S. H. (1959), *J. Appl. Bact.*, 22 (1), 159–173 (37).

Figure A1.1



A — 1 litre Thermos brand flask.

B — Rubber bung (drilled to accommodate 2 glass tubes — push fit, stirrer and 3mm ø vent-hole).

C — Thermocouple Tube 7mm OD / 5mm ID 30 cms long glass. Thermocouple hot junction to be positioned at the lower end of the tube.

D — Steam Sparge Tube 7mm OD / 5mm ID 30 cms long, glass.

E — Stirrer 14 gauge brazing wire with 25mm square x 20 gauge paddle brazed to end.

F — 'T' in steam line to sterilizer.

G — Reducing Bush.

H — Capillary Probe brazed into union

J — 'O' ring union fitting.

K — Rubber Tube 8mm OD 30cms long.

The apparatus shown includes

"Thermos" brand 1-litre flask. (This has a plastic case.)
Rubber bung (drilled to accommodate 2 glass tubes—push fit; stirrer and 3mm vent hole).
Two lengths of 7mm OD/5mm ID glass tubes 30cm long.
One length of 8mm OD/ID rubber tube 30cm long.
One length of 14-gauge brazing wire with 25mm square×20-gauge paddle brazed to end.

Appendix 1 continued

Since the increase in mass and temperature is known, the dryness fraction can be determined from a heat balance.

A typical equation is shown below.

Let T_1 = Temperature of the water at the beginning of the test (°C).
T_2 = Temperature at the end of the test (°C).
T_3 = Temperature of the steam (°C).
L = Latent heat of the steam at T_3 (from tables) (kJ/kg).

D = Dryness fraction of the steam.
Ws = Weight of thermos at the beginning of the test (kg).
Wf = Weight of thermos at the end of the test (kg).
Wc = Weight of condensate collected (kg).
Ww = Weight of initial water charge (kg).
Wt = Total weight of thermos plus bung, tubing, etc., but excluding water.
W_1 = Weight of the glass thermos (consider only the glass, DO NOT include weight of canister) (kg).
W_2 = Weight of the glass tubing (kg).
W_3 = Weight of the rubber bung and tubing (kg).
W_4 = Weight of brass stirrer (kg).
W_5 = Weight of entire flask (canister but not lid) (kg).

S_1 = Specific heat of glass = 650 (nom.) J/kg °K.
S_2 = Specific heat of rubber = 2009 J/kg °K.
S_3 = Specific heat of brass = 370 J/kg °K.
S_4 = Specific heat of water = 4180 J/kg °K.

NOTE: It is assumed that the effective weight of the thermos flask, rubber bung and tube are respectively 75 per cent and 25 per cent.

Heat gained by the thermos =
$0{\cdot}75\ W_1(T_2 - T_1) \times S_1$ where S_1 = specific heat capacity of glass.

Heat gained by glass tubing =
$W_2(T_2 - T_1) \times S_1$

Heat gained by the rubber bung and tubing =
$0{\cdot}25\ W_3(T_2 - T_1) \times S_2$ where S_2 = specific heat capacity of rubber.

Heat gained by the stirrer =
$W_4(T_2 - T_1) \times S_3$ where S_3 = specific heat capacity of brass.

Heat gained by the water in the flask =
$Ww(T_2 - T_1) \times S_4$ = specific heat capacity of water.

∴ total heat gained =
$(T_2 - T_1)\ (0{\cdot}75\ S_1\ W_1 + S_1\ W_2 + 0{\cdot}25\ S_2\ W_3 + S_3\ W_4 + S_4\ Ww)$ equation 1.

TOTAL HEAT LOST = $Wc \times D \times L + Wc\ (T_3 - T_2)\ S_4$ equation 2.
Wt (weight of complete flask + stirrer, etc.) = $W_5 + W_2 + W_3 + W_4$
$Ww = Ws - Wt$
$Wc = Wf - Ws$

∴ rewriting and solving for D.

Dryness fraction D =

$$\frac{(T_2 - T_1)\ (0{\cdot}75\ S_1\ W_1 + S_1\ W_2 + 0{\cdot}25\ S_2\ W_3 + S_3\ W_4 + S_4\ (Ws - Wt)) - (Wf - Ws)\ (T_3 - T_2)\ S_4}{(Wf - Ws)\ L}$$

Appendix 1 continued

*Table A*1.1 **Capillary Pitot Tube Diameters**

Steam Pressure	*Diameter*
7 bar	0·71 mm bore
4 bar	0·96 mm bore

Using the apparatus shown in Fig. A1.1 and the sizes given for the various components and taking account of the order of magnitude of the various elements, the equation may be reduced further with a loss of accuracy which should not exceed 1–2 per cent.

Let T_1 °C be the initial temperature of water in the flask.
T_2 °C be the final temperature of water and condensate in the flask.
T_3 °C be average steam temperature during sampling period.
L kJ/kg be latent heat of steam at T_3—from steam tables.
Ws kg be the weight of flask, stirrer, etc., and water charge.
Wf kg be the weight of flask, stirrer, etc., water and condensate.

$$D = \frac{(T_2 - T_1)\,(4{\cdot}18Ws - 2{\cdot}544)}{L\,(Wf - Ws)} - \frac{(T_3 - T_2)\,4{\cdot}18}{L}.$$

LIBRARY AND INFORMATION SERVICE
POLYTECHNIC OF NORTH LONDON
HOLLOWAY ROAD
LONDON N7 8DB

Appendix 2

Instruments to be mounted on sterilizers and for testing and commissioning sterilizers

Instruments to be mounted on the sterilizer and to be visible to the operator

General

A2.1 Where more than one gauge or instrument is fitted in the same area, every effort should be given to obtain a uniform appearance, e.g. circular pressure and temperature gauges.

A2.2 The errors produced in temperature and pressure measurement using either indicators or recorders arise from a number of factors. Some of these are inherent in the design, age and condition of the measuring equipment. Others are brought about by the conditions on site, the day-to-day variations in atmospheric conditions and the skill and experience of the operator. Still others arise from the permissible variations in the thermocouple alloys, and even the positioning of the thermocouples within the load can produce misleading readings. Loose terminals and imperfect plug and socket connections will also cause errors.

A2.3 Every effort should be made to eliminate or minimize these errors by attention to detail in design, effective maintenance and skill in the application and use of the instruments.

A2.4 The levels of accuracy stated in this Appendix assume that the instruments and controllers are designed, chosen and located in a manner which will ensure a long trouble-free life under the varying conditions of temperature and humidity to which they will be subjected. The normal ambient temperature in the plant room with the plant idle may be between 10°C and 30°C, and up to 40°C with the plant running.

A2.5 All instruments should comply with the relevant British Standard. The sterilizer manufacturers must carry out adjustments to the instruments on site as necessary so that the additional requirements of this Appendix can be met with the "plant running" conditions normally prevailing on site. Accurate test instruments and test procedures for site calibration are described in A2.33 to A2.76 of this Appendix.

Indicating thermometers

A2.6 Indicating thermometers must be either Type "1", Type "2" or Type "3" as follows:

a. *Type* 1. Dial type expansion thermometers, liquid or gas filled or, in the case of bench top machines and hot air sterilizers, vapour pressure instruments.

The scales of the last-named are non-linear, and for this reason vapour pressure instruments are not preferred. The thermometers should be generally in accordance with B.S.5235 (44) and as in Table A2.1 below.

b. *Type* 2. Indirect electrical indicating instruments in accordance with B.S.5164 (38).

These are calibrated either for resistance elements or for a particular type of thermocouple. It should be noted that thermocouple instruments indicate correctly only when used with the class of thermocouple for which they are calibrated (see A2.55 to A2.61 of this Appendix). Instruments for mounting on machines must be as in Table A2.2 below.

NOTE: Thermocouples to B.S.4937 : Part 3 (41) (iron/copper-nickel) Type J may not be suitable for

*Table A*2.1—**Scales for indicating thermometers**

Standard requirements		*Exceptions for bench-top electrically heated unwrapped instrument and utensil sterilizers*	
		Single function instruments	*Dual function*[a] *instruments*
Nominal size (dia.)	100 mm.	50 mm.	50 mm.
Minimum scale length	160 mm.	90 mm.	50 mm.
Scale range (max.)	150°C[b]	150°C	150°C
Graduations over effective range	2°C	5°C	5°C

[a] These indicate temperature and pressure but must have separate sensors for temperature and pressure.

[b] 200°C for hot air sterilizers.

Table A2.2—**Selection of instruments**

Calibrated for use with	*Relevant British Standard*	
Resistance elements, Grade II	B.S.1904 (39) or B.S.1041: Part 3 (40)	
Thermocouples in accordance with B.S.1041: Part 4 (40)	B.S.4937: Part 4 (42)	Nickel-chromium/ nickel-aluminium Type K
	B.S.4937: Part 5 (43)	Copper/copper-nickel ("copper-constantan") Type T

use here because of the corrosion problem. Where a scale is used it should have a scale length of not less than 120 mm.; however, the newer style of "ribbon" indicator with a scale length of 100 mm. is acceptable because of the better resolution with this type of scale. The scale should be calibrated 0–150°C (0–200°C for hot air sterilizers) with gradations at 2°C intervals. (If digital instruments are used the maximum increment to be displayed should be 0·5°C.) Semi-conductor resistance elements (including thermistors) may be used where the normal maximum temperature does not exceed 160°C. The instruments must have broken sensor protection giving full scale deflection. Where the instrument is to be used to provide a limited control function the broken sensor protection must fail safe; the sterilizer manufacturer should state whether up-scale or down-scale drive is required on failure.

c. *Type* 3. Dial type expansion thermometers of the bi-metallic type.

These may be suitable for use in certain situations where direct connection between sensing and indicating elements is possible (e.g. without the use of capillary tubes). This type is often sensitive to vibration, e.g. by door slamming, and must, therefore, be of a design which allows for such treatment. *They will normally be suitable for use only on hot air sterilizers.* In this situation alone they may also be used to operate in conjunction with timers and door interlocks but not to control the chamber temperature. They must be of the type with the element sealed in a stainless steel stem. There is no British Standard for this class of instrument but they should comply with B.S.5235 (44) as far as practicable. Mercury-in-glass thermometers may also be used on hot air sterilizers. They should be generally in accordance with B.S.1704 (45).

A2.7 Table A2.3 indicates *ideal* scale ranges for the various types of sterilizer, the actual scale will vary from manufacturer to manufacturer.

A2.8 The indicating instrument may sense the temperature at a point indicated in Table A2.4 below.

Table A2.3 **Typical acceptable ranges for thermometric scales**

Type of Sterilizer	*Scale °C*
Fluids	40–160
Porous loads	60–180
Unwrapped instruments and utensils	60–180
Hot air	50–200

NOTE: Separate systems must be used for:

(i) Indicating thermometer (or temperature indicator/controller where permitted in A2.10).

(ii) The recorder.

(iii) Temperature interlock for fluids sterilizers. The interlock to prevent opening of the door with load temperature in excess of 80°C should be controlled only by means of a load simulator and not directly from a load bottle.

A2.9 The maximum error should not exceed 1°C at the sterilizing temperature which, for this purpose, may be taken as the mean of the limits of a particular sterilizing temperature range, e.g. 136°C for a $134 \pm {}^{4}_{0}$°C range. The permissible error stated here is for an instrument mounted in a vertical position in an ambient temperature of 20°C ± 5°C with the difference in level between the sensor and instrument as it occurs on the sterilizer. This degree of accuracy will not be achieved if the ambient temperature is outside the limits stated; the permissible error in such circumstances is given in the British Standards. The instrument should incorporate a means of adjustment for setting on site so that the accuracy required at the mean sterilizing temperature is achieved (see A2.5).

A2.10 The indicating thermometer may only be used for control purposes if the control function does not

Table A2.4 **Sensor locations for indicating thermometers and temperature recorders and controllers**

Type of sterilizer	*Chamber drain*	*Coldest part of chamber steam space (or chamber free space)*	*Air vent*
Porous load	YES	NO	N.A.
Fluids with chamber drain	YES	NO	N.A.
Fluids without chamber drain	N.A.	YES	YES
Unwrapped instruments and utensils, with chamber drain	YES	NO	N.A.
Unwrapped instruments and utensils, without chamber drain	N.A.	YES	YES
Hot air	N.A.	YES[a]	YES

[a] This may be either in the air circulation system or in a position agreed with the manufacturer; this may not, however, be the coldest part of the chamber (the coldest part of the chamber or load may be up to 5°C lower—see paragraph A13.16 d.).

affect the indication of the temperature. This limitation need not apply in the case of a hot air sterilizer provided that the effect of any control function is restricted to a *depression* in indication of a rising true temperature not exceeding 1·5°C or 1·5 per cent of the scale span, whichever is the lesser.

Pressure gauges

A2.11 Pressure gauges should preferably be of the bourdon tube type and be in accordance with B.S.1780, Part 2 (46) for Class 1 instruments. It is the normal practice of many sterilizer manufacturers to fit pressure gauges without syphons, although the British Standard recommends that a pressure gauge should not be directly exposed either to steam or to working fluid at a temperature in excess of 100°C. For these reasons the accuracy stated for the scale range cannot be guaranteed, though sterilizer manufacturers can ensure that the stated accuracy can be achieved by calibration at the operating temperature. There is little practical evidence to support the omission of syphons on modern sterilizers and it may now be preferable to fit them, in order to maintain the British Standards accuracy of the instruments. The instrument should incorporate a means of adjustment for setting on site, so arranged that authorised persons may be able to make the adjustment without having to dismantle the instrument.

A2.12 The size and length of scale should be as in Table A2.5.

A2.13 The scale should be as in Table A2.6

A2.14 The error in pressure indication should not exceed ± 1 per cent of the scale range at the sterilizing temperature which, for this purpose, may be taken as the mean of the limits of a particular sterilizing temperature range, e.g. 136°C for a 134 $\pm {}^{4}_{0}$°C range.

NOTE: It is essential that where two pressure gauges are connected to the same source of pressure (e.g.

Table A2.5 **Size and scales (length) for pressure gauges**

Standard requirements		*Exceptions for bench-top electrically heated unwrapped instrument and utensil sterilizers*	
		Single function instruments	*Dual function instruments*[a]
Nominal size (dia.)	100 mm.	50 mm.	50 mm.
Minimum scale length	160 mm.	90 mm.	50 mm.

[a] These indicate both pressure and temperature but must have separate sensors for pressure and temperature.

Table A2.6 **Scales for dial type pressure gauges**

Duty	*Scale (as defined in* B.S.1780: Part 2)	*Graduation intervals (mbar)*	
		Nominal 100 mm. *dials*	*Nominal* 50 mm. *dials*
Leak testing	0–150 mbar (abs) maximum	2	(a)
Fluids	0 to 2·5 bar (b)	100	(a)
Porous loads chamber	— 1 bar to + 5 bar	200	(a)
Unwrapped instruments and utensils (chamber)	(— 1 bar to + 5 bar) OR (0 to 4 bar)	200 200	(a)
Porous loads and unwrapped instruments and utensils (jackets)	0 to 4 bar	200	(a)
Electrically heated bench top unwrapped instruments and utensils sterilizers—single function gauges and dual function gauges(c)	0 to 4 bar	200	200

(a) This size of instrument is unsuitable for this duty.
(b) May be 0 to 4 bar for non-rigid containers.
(c) Dual function gauges are combined temperature and pressure instruments.

inter-connected chamber and jacket) they should be set on site to indicate identical pressure within the above limits of accuracy.

A2.15 The leak rate testing gauge should respond to any change of pressure exceeding 1 mbar.

A2.16 Absolute pressure gauges for leak rate testing should be in accordance with B.S.1780 : Part 2 as far as construction and general principles of operation are concerned. (There is no British Standard for this type of gauge.) The gauge should be suitable for operation either when exposed directly to steam at 2·8 bar or when connected to the chamber via an automatic isolating valve. This valve must prevent exposure of the gauge to steam and to pressures in excess of atmospheric pressure.

NOTE: The continuing availability of barometrically compensated absolute pressure gauges within reasonable costs is doubtful. Instrumentation for leak testing is under review. A vacuum gauge with sensitivity in accordance with A2.15 should be adequate. The variation in vacuum achieved by the machine under various conditions of atmospheric pressure should be indicated by a coloured band or similar means. Calibration may be over the entire range of scale or over a 15 mbar range inscribed on a rotating bezel ring.

Temperature recorders and combined temperature/pressure recorders

A2.17 A temperature recorder should be fitted to monitor the performance of each sterilizer for porous loads, each sterilizer for fluids in sealed containers and each hot air sterilizer. It is not mandatory to fit any recorder to a sterilizer for unwrapped instruments and utensils but there are many situations in which its use can be justified, particularly in some operating theatres.

A2.18 Recorders should not be used to control either the temperature or the pressure in the chamber or any safety interlocks.

A2.19 All recorders should incorporate a means of adjustment for setting on site.

A2.20 The thermometric measuring system should sense the temperature at a point as indicated by one of the following means.

a. Indirect acting electrical, either with resistance elements or with thermocouples as in Table A2.2. Semi-conductor elements (including thermistors) may be used where the normal maximum temperature does not exceed 160°C; they are not, therefore, normally suitable for use in hot air sterilizers.

b. Liquid expansion, generally in accordance with B.S.5235 and B.S.1041. (Vapour pressure instruments are unsuitable for this application.)

A2.21 The recorded temperature should be within $\pm$ 1°C at the sterilizing temperature which, for this purpose, may be taken as the mean of the limits of a particular sterilizing temperature range, e.g. 136°C for a 134 $\pm {}^{4}_{0}$°C range. The temperature chart should be scaled with a maximum range of 150°C (200°C for hot

air sterilizers) and a minimum range of 100°C, with lines at intervals representing a division not exceeding 2°C (5°C for hot air sterilizers).

A2.22 Electrical instruments should comply generally with B.S.5164, with broken sensor protection. Where the instrument is to be used to provide a control function (see A2.18) the broken sensor protection should fail safe; the sterilizer manufacturer should therefore state whether up-scale or down-scale drive on failure is required.

A2.23 The pressure measuring system on a combined temperature/pressure recorder will normally incorporate a bourdon tube and be in general accordance with B.S.1780, Part 2 for Class 1 instruments. The problem of connecting pressure recorders is the same as that arising with pressure gauges and the solution is similar (see A2.11).

A2.24 Other pressure recording systems may be used providing they are suitable for the application and are no less accurate than the approved bourdon system.

A2.25 The error in recorded pressure should not exceed ± 1 per cent of the scale range at the sterilizing temperature which, for this purpose, may be taken as the mean of the limits of a particular sterilizing temperature range, e.g. 136°C for a 134 $\pm {}^{4}_{0}$°C range. The pressure measuring system should be suitable for the ranges specified for pressure gauges in Table A2.6.

A2.26 On combined instruments the scale lines on the chart should be common for the temperature and pressure record, the temperature record taking precedence for the major scale lines.

A2.27 The recording charts may be either circular or strip charts (preferably the latter) and should provide a permanent and immediately visible record. If strip recorders are used, they should perferably incorporate either a *tear-off* facility or be suitable for *Z-fold* charts. It will be necessary to remove the chart on completion of the process so that *roll on* or *pull through* is required. Circular charts should preferably be not less than 240 mm. diameter, with a radial scale length not less than 100 mm. Strip charts should not be less than 90 mm. wide. Recorders printing on cards may offer an alternative, but in this case it is advisable to provide an interlock to prevent commencement of the cycle until a card is inserted. (The record is, unfortunately, not normally immediately visible with card instruments.)

A2.28 Selection of an appropriate chart speed will be dependent upon the type of recorder chosen and the process being monitored. Separate charts for each cycle are preferred when medicinal products are sterilized (see Appendix 4, paragraph A4.49k). Chart speeds should be as in Table A2.7.

Table A2.7 **Chart speed for temperature recorders mounted on sterilizers**

Type of Recorder	*Circular*		*Strip*	
Chart Speed	*Hours/ revolution*		*mm/min*	
Process	*Max.*	*Min.*	*Max.*	*Min.*
Porous load	3	2	20	5
Fluids, rapid cooling	3	2	8	2
Fluids, natural cooling	3	2	2	1
Hot air	12	6	2	1

A2.29 Pressure recording systems of the bourdon tube type can normally be fitted to instruments using either electronic or expansion thermometric systems but, as a rule, they are used only with circular chart recorders.

A2.30 Pressure transducer systems are compatible with strip chart recorders but are not generally available within the price range of a comparable mechanical system.

Cycle stage indicator

A2.31 Means must be provided to indicate each stage in progress at any time, e.g. *air removal, sterilizing, cycle completed.*

Cycle counter

A2.32 A four-digit cycle counter must be provided to indicate the cumulative total of completed cycles regardless of whether they are sterile or non-sterile. The counter should be tamper-proof or sealed, and be non-resettable.

Instruments for test purposes

Temperature recorders—general

A2.33 The requirement embraces instruments used for:

a. commissioning sterilizers;

b. re-commissioning sterilizers which have undergone major overhaul;

c. periodic testing of sterilizers in service.

Table A2.8 **Specification for temperature recorders required for test purposes**

	Duty[a]	*Usual chart width mm.*	*Minimum number of channels*	*Minimum chart speed mm./min.*	*Intrinsic error as in Table 1 of B.S.5164, 1975 (% of scale span)*	*Dead*[a]*band (% of scale span)*
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.	Commissioning, re-commissioning and yearly testing of fluids and hot air sterilizers	250	12	5	0·5	0·25
2.	Commissioning, re-commissioning and yearly testing of other sterilizers	250	3	20	0·5	0·25
3.	Other periodic testing of fluids and hot air sterilizers	100	3	5	1·0	0·5
4.	Other periodic testing of other sterilizers	100	3	20	1·0	0·5

(a) The Sterilizer Engineer uses the instrument for duties 1 and 2, the Maintenance Engineer uses the instrument for duties 3 and 4.

A2.34 The instruments should be of the indirect acting electrical type, for use with thermocouples and generally in accordance with B.S.5164. Instruments calibrated with iron/copper-nickel thermocouples conforming with B.S.4937: Part 3, are not suitable for use with sterilizers because of corrosion problems. (The use of resistance elements is impracticable for testing some sterilizers.) Details of the British Standard requirements are in Table A2.8. They relate to the instrument only, i.e. they do not allow for errors arising from the thermocouples. Facts relating to the accuracy of measurement achieved in practice are given in subsequent paragraphs (see also paragraph A2.38).

A2.35 The two instruments will have the intrinsic accuracy stated in Table A2.8 only under the reference conditions stated in Table 3 of B.S.5164. These include those in Table A2.9.

Table A2.9 **Some basic reference conditions for instruments in B.S.5164, 1975**

Influence quantity	*Reference condition (unless otherwise stated)*	*Tolerance for a single reference value*
Ambient temperature	20°C	± 1°C
Relative humidity	50%	40% to 60%
Supply voltage	Rated	± 1%

A2.36 The accuracy of the two instruments is permitted to vary from the figures in column (6) of Table A2.8 for wider ranges in the reference conditions. The method and extreme limits permissible are stated in Table 8 of B.S.5164. The additional error permitted by the extreme limits is shown in Table A2.10 for the more usual influence quantities. The permissible error permitted for conditions within the extreme limits and for other influence quantities should be calculated as indicated in B.S.5164. The permissible limit of error for automatic cold junction compensation is not stated in the British Standard but a typical figure is also quoted in Table A2.10 for completeness.

A2.37 The permissible errors may be aggregated statistically, but the instrument should be fitted with span and zero adjustment controls for the purpose of site calibration.[a] The errors shown in the Table A2.10 are the maximum allowable; most instruments are capable of achieving greater accuracy (see A2.38).

A2.38 The instrument should be calibrated at the test site before a test is commenced. When this is done the combined error arising from instrument and thermocouple is unlikely to exceed 0·5°C[b] for the Sterilizer Engineer's instrument and 0·75°C[b] for the Maintenance Engineer's instrument.

A2.39 Ideally these instruments should have interchangeable scales and circuitry, calibrated 0–150°C and 50–200°C, with the range change made, preferably, by an integral switch. If, for any reason, it is proposed

(a) Defined as: The range within which the measured quantity may be varied without initiating a movement of the indicating or recording device.

(b) These errors may be increased as a result of cold junction compensation error. The importance of stable temperatures and avoidance of draught is emphasized.

Table A2.10 **Additional error permitted for extreme limits**

Influence quantity	*Limit of permissible range*	*Additional permissible error at limit of permissible range of a single influence quantity*	
		Sterilizer Engineer's commissioning instruments (% of scale span)	*Maintenance Engineer's periodic testing instruments (% of scale span)*
Ambient temperature	± 10°C	0·1	0·2
Rated voltage of power supply	+ 5% to — 15%	0·125%	0·25
Automatic cold junction compensation (typical—not covered in the British Standard)	—	0·04°C per °C change	0·04°C per °C change

to use a single scale instrument, this should be calibrated 0–200°C.

A2.40 The instrument should provide, simultaneously, a scale indication and a permanent and immediately visible record with the cover closed.

A2.41 The record should be colour coded or colour coded and numbered. Six colours are usually adequate, provided they are printed in two different symbols.

A2.42 Each instrument should be used only with the class of thermocouples for which it is calibrated.

A2.43 The commissioning, re-commissioning and annual test requirement can best be met by a 12-channel recorder. It may be used for all types of sterilizers. For all periodic testing, except the annual test, a 3-channel instrument may be used.

A2.44 The 12-channel instruments are all very expensive, very large and very heavy.

A2.45 All these instruments need considerable care in handling and transport if they are to maintain their accuracy; they deteriorate if not regularly used and for this reason should not normally be held at hospital or District level.

Particular details of 12-channel temperature recorder

A2.46 The instrument should have a maximum dotting interval of 3 seconds per point, i.e. a rated duration of cycle not exceeding 36 seconds when recording 12 channels.

A2.47 When a test requires fewer channels than those available in the instrument, it is desirable to ensure that the specified dotting interval between monitored positions is not exceeded, i.e. when three positions are to be monitored the effective scan time does not exceed 9 seconds, or if two positions are to be monitored the effective scan time does not exceed 6 seconds. It is possible to accomplish this by various means, such as:

a. using one thermocouple for each monitored position and inter-connecting channels in parallel groups by identical thermocouple wire;

b. changing printed circuit boards in the instrument (the instrument should be recalibrated whenever a printed circuit board is changed).

A2.48 In all cases it is helpful if the printing head can be changed, so that each record is in one colour only (although it may be made up of a variety of symbols).

Particular details of 3-channel temperature recorder

A2.49 The instrument should have a maximum dotting interval of 10 seconds per point, i.e. a total rated duration of cycle not exceeding 30 seconds when recording 3 channels. If the instrument is required to monitor one or two positions, the rated duration of the cycle should be reduced to 10 or 20 seconds, preferably by cross-connecting the channels in parallel or alternatively by using more than one thermocouple to monitor one position. In either case it is helpful if the printing head can be changed, so that each record is in one colour only.

A2.50 When monitoring two points only, e.g. the drain and centre of pack in porous load tests, it is desirable that the pack and not the drain is recorded twice in a 3-channel scan.

A2.51 There is some merit in using a continuous trace instrument for these tests.

Test thermometers

A2.52 Thermometers should be Laboratory Thermometers, conforming with B.S.593 (47) and of the partial

immersion type. The most appropriate instruments will be the F 50C/100 (range—2°C to 52°C), the F 100C/100 (range—48°C to 102°C), the F 150C/100 (range—98°C to 152°C) and the F 175C/100 (range—123°C to 177°C). They should be specified as having a stem diameter of not less than 7·0 mm. They are designed for 125 mm. immersion and are 405 mm. long.

WARNING: NO MERCURY-IN-GLASS THERMOMETER SHOULD BE USED INSIDE A STEAM CHAMBER.

Test pressure gauges

A2.53 These may be bourdon test gauges conforming with B.S.1780: Part 2. If they are not designed for direct connection to steam at 2·8 bar they should be connected via a syphon. They should be calibrated 0 to 150 mbar absolute and — 1 bar to 0 for vacuum gauges and 0 to 2·5 bar for pressure gauges. They should be scaled as shown in Table A2.11.

Table A2.11 **Scales for test pressure gauges (dial type)**

Scale	*Graduations*
0 to 150 mbar absolute	0·5 mbar
—1 bar to 0	5 mbar
0 to 2·5 bar	20 mbar
—1 bar to 4 bar	25 mbar

A2.54 The minimum scale length should be 260 mm. and the nominal size not less than 150 mm. diameter. They should be tested, as in paragraph 5.2.1 of B.S.1780, by a recognised testing laboratory and the error should not exceed one quarter of 1 per cent of the maximum scale range. Other test gauges may be used, provided they are suitable for the purposes and provided they are no less accurate than is prescribed for bourdon test gauges.

Construction and use of thermocouples

A2.55 Thermocouples should conform with B.S.4937: Part 4 (nickel-chromium/nickel-aluminium) or Part 5 (copper/copper-nickel[a] = *copper/constantan*). The tolerance on Part 4 thermocouples is high (± 3°C) when compared with that allowed for those in Part 5 (± 1°C up to 100°C and ± 1 per cent from 100°C to 400°C) and for this reason copper/constantan thermocouples are usually preferred for test instrument use.

A2.56 It is essential to use thermocouple wire of known output which has previously been checked off site. This problem of purchasing presents difficulties and draws attention to the inherent variations in the performance of every reel of thermocouple wire and part thereof, as well as the errors arising from imperfections in the actual jointing techniques.

A2.57 Thermocouple wire is available, marked to show the limits of variation of the reel from the figures given in the British Standard. The variation will have been established by the manufacturer, by testing samples from both ends of the full reel, and for "*SELECTED*" wire this is typically (for copper/constantan) of the order of 0·015 millivolts, which is equivalent to 0·4°C at 20°C and 0·3°C at 134°C. "Selected", rather than "Standard", wire should be used for this reason.

A2.58 The wire should be single strand, not exceeding 0·7 mm. diameter over the covering and single core or twin. Tracking of steam along the outside of the wire to the centre of the Bowie/Dick tape test pack may be a problem with the bulkier twin core wire, thus defeating the object of the test. If it is used it will be necessary to take extra care to minimize disturbance of the towels. Steam or fluid may be forced through the wire sheath, particularly fluid, when thermocouples are used in bottles. The sheath should be stripped back for a few inches before connecting the wires to the recorder so that any droplets forming where the sheath has been terminated fall clear of the instrument. Twin core wire is usually preferred because it is easier to handle and more durable than single core wire.

A2.59 Thermocouples should preferably be argon-arc welded or micro-welded; alternatively they may be suitably cleaned and twisted, or crimped together with purpose-made ferrules, to form the hot junction. Brazing, silver brazing and welding with filler rods may be no more reliable in respect of accuracy than twisting or crimping. If welding is not employed (and it rarely is in the field) it is good practice to use new thermocouples each time a sterilizer is monitored. If reasonable care is taken, especially with outer sheathed wire, it is often possible to re-use the wire several times, provided any twisted or crimped joints are re-made. Thermocouples should not be fitted with a heat sink, neither should they be "slugged".

A2.60 Three typical methods of introducing thermocouples into sterilizer chambers are illustrated in Figures A2.1, A2.2 and A2.3. Some manufacturers adopt other solutions, some of which are to be discouraged because they prevent the removal of individual thermocouples. In those machines having no thermocouple entry socket, entry may be made via a tee which

(a) This supersedes B.S.1828 (48) and is identical with the USA standard. There are significant differences in emfs. The difference ranges between approximately 0·5°C at 73°C and 1·5°C at 160°C. B.S.1828 should be referred to for existing stocks to that standard.

can usually be inserted into a service entry pipe (e.g. steam supply pipe) to the chamber. The thermocouples should not be introduced through the door seal except as the last resort.

A2.61 Entry of thermocouples through bottle caps may be made by means of a trochar and cannula, but any other suitable method may be used. It is essential that the sealing of the bottle remains effective with the thermocouples in position.

Calibration of testing instrument at sterilizer test site—general considerations

A2.62 A functional test of the temperature recorder should be carried out on site as recommended by the makers after any range change, and after span and zero adjustment (see A2.37) by one of the following methods:

a. thermocouple immersed in oil bath;

b. potentiometer and standard cell;

c. milli-volt source.

NOTE: The technique employing thermocouples immersed in boiling water is only of use for rough checking purposes: it may be affected by the pH of the water. If the method has to be adopted, the calibration should be checked against a standard thermometer, immersed with the thermocouples, using distilled or purified water. The normal extremes of atmospheric pressure result in a change in the boiling point of approximately ± 2°C. Also, any increase of 150 m. above mean sea level will reduce the boiling point by approximately 0·5°C.

A2.63 All electronic test instruments should be allowed a period of at least 2 hours within the test site environment to enable the instruments to stabilize with the mains switched on.

A2.64 All thermocouples used should be checked again after completion of the tests on the sterilizer before they are disconnected from the instrument (see A2.81).

Calibration of test instrument by oil[a] bath

A2.65 There are two main versions of the oil bath; the first is one in which the oil is in a bath, usually with a magnetic stirrer or fluid circulator, and the second, which is to be preferred, where the oil is held in pockets in a large, electrically heated aluminium block.

NOTE: If the thermocouples are not welded there may be difficulty in achieving the prospective degree of accuracy because of the insulating property of the oil. For this reason additional care is required if mechanical jointing is proposed, and this is the reason why micro-welding or argon-arc welding is the preferred method (see A2.59).

A2.66 The recorder is first adjusted in accordance with the maker's instructions. This usually involves zero and span adjustments. Any range change should be effected before these adjustments are made.

A2.67 The thermocouples are immersed in the heated oil bath together with a standard thermometer. Support clamps are available and may be used with advantage to hold the thermocouples and thermometer closely together. The stirrer should be used to maintain a uniform oil temperature, and readings should be taken with the temperature on a rising cycle and at the sterilizing temperature. It may be necessary to add small quantities of cold oil to ensure that the readings are taken with rising rather than falling oil temperature.

NOTE: In practice this is difficult to effect and it may be more convenient at this stage to check one of the thermocouples only (see A2.81).

A2.68 The electrically heated block form of oil bath has the advantage of greater portability since it is necessary only to use sufficient oil to ensure intimate contact between thermocouples, the standard thermometer and the test block.

A2.69 The oil-bath method of calibration also suffers from the lack of uniformity in the thermocouple wire referred to in A2.56. The inherent inaccuracy of the potentiometer is eliminated but both the hysteresis of the mercury and glass thermometer, and the temperature gradient within the oil, can give rise to errors unless great care and skill are applied. If these errors can be eliminated or discounted, the limits of accuracy are those imposed only by the dead band of the recorder.

Calibration of test instrument by potentiometer and standard cell

A2.70 The potentiometer used for this purpose should have an error not exceeding 0·1 per cent of the scale range, or 5 micro-volts, whichever is the greater.

A2.71 It must first be standardized in accordance with the maker's recommendations. This usually involves adjustment of the cold junction temperature setting in accordance with the reading of a thermometer on the instrument itself. The potentiometer is then set to give a milli-volt output corresponding to the sterilizing temperature of the test. This milli-volt setting is taken from tables given in the appropriate part of B.S.4937. For example, if copper/constantan thermocouples are used, the tables in Part 5, 1974, are consulted and the output given for 134°C is 5·908

[a] The *oil* is normally a silicone fluid, e.g. that used for the Basic Performance Test for Hot Air Sterilizers (see Appendix 13).

milli-volts (mv.). From this figure must be subtracted the emf corresponding to the cold junction temperature read on the thermometer on the recorder. If the cold junction temperature is 20°C the cold junction emf (taken from the same tables) is 0·789 mv. The potentiometer is then set to give an output of 5·908 — 0·789 = 5·119 mv.

A2.72 The recorder is then adjusted in accordance with the maker's recommendations (see A2.62). The milli-volt output from the potentiometer (in this case 5·119 mv.) is connected to the input terminals of one channel on the recorder and the instrument is adjusted in accordance with the maker's instructions so that it indicates 134°C.

A2.73 In order to minimize the effect of the inherent error of the thermocouples, it is desirable to make up (off the sterilizer site) a set (of 12 or 3 plus two matching spares) from the same reel of wire and chosen by test against a potentiometer so that they have, as near as possible, an identical performance.

A2.74 The average emf output of the set of thermocouples should be measured by the potentiometer, with one of them attached to a standard thermometer in an oil bath at the sterilizing temperature (see A2.65–A2.69). For example, with the oil bath at 134°C the difference between the thermocouple emf and British Standard standard thermocouple emf is found to be 0·012 mv. (5·131 mv. measured, 5·119 mv. standard). This variation is actually equivalent to + 0·25°C. The recorder should then be re-set, on the sterilizer site, to indicate 134°C with an input of 5·131 mv. from the potentiometer (i.e. to indicate 133·75°C at 5·119 mv.).

A2·75 It is recognized that in many instances it will not be practicable to prepare thermocouples off the sterilizing site and, in such cases, the calibration of the recorder should be done by one of the other methods referred to in A2.62.

A2.76 The limits of accuracy of calibration by the potentiometer method are a combination of those imposed by the accuracy of the potentiometer itself and the dead band of the recording instrument. The potentionmeter method may be unsuitable for recorders having a wide dead band (i.e. greater than 0·15 per cent) because the combined errors may be unacceptable. A dead band width of 0·15 per cent of scale span is acceptable.

Calibration of test instrument by millivolt source

A2.77 A standard laboratory source is used for this purpose in lieu of the potentiometer and standard cell. The procedure to be followed is similar to that in A2.70—A2.76.

Calibration and maintenance of testing instruments off site

A2.78 Routine calibration of temperature recorders should be carried out with a potentiometer and standard cells designed for the purpose. The instruments should be re-calibrated by the makers or by an appropriate standards laboratory at six-monthly or at closer intervals, as suggested by the manufacturers.

A2.79 Routine checking of the accuracy of the test pressure gauges should be carried out by a recognized testing laboratory and as recommended in B.S.1780: Part 2.

A2.80 Maintenance of temperature recorders should be carried out in accordance with the makers' instructions and should be followed by re-calibration as recommended by them.

Calibration of instrument on site for test purposes

A2.81 The following procedure has been found satisfactory.

a. Calibrate test instrument and one of the thermocouples by the oil bath method in A2.65–A2.69 at the sterilizer temperature expected prior to arrival on site. Ideally this should be undertaken in similar ambient conditions to those expected on site. Adjust recorder as required.

b. Check this calibration with a *millivolt source* as described in A2.77 and note the indicated temperature difference between that obtained with the oil bath. This is the thermocouple error which should be noted.

c. At site apply *millivolt source* to recorder and check reading obtained previously as a check on the recorder and millivolt source.

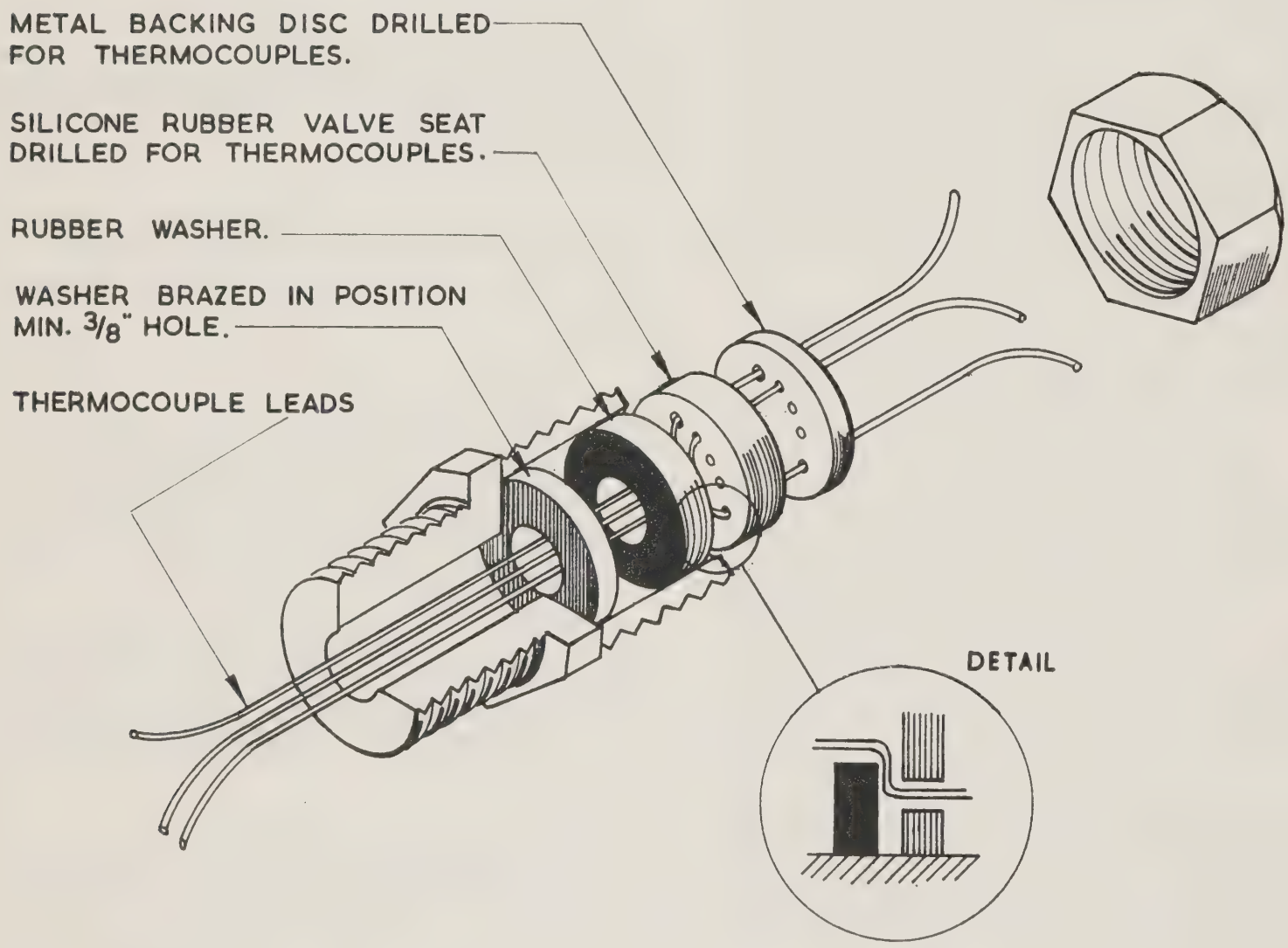
d. Connect all thermocouples and expose the hot junctions of the bundle in the chamber space to check *tracking* of the group at the sterilizing temperature. The thermocouple error should be unchanged from that obtained off site.

e. If discrepancies are noted it may be necessary to check individual calibration with the oil bath (on or off site) or check those thermocouples which produce anomalous readings.

NOTE: The use of the *millivolt source* at the beginning and end of a series of tests produces a check on the continuing integrity of the instrumentation; similarly the thermocouple bundle should be exposed to steam in the chamber to check "tracking".

Figure A2.1

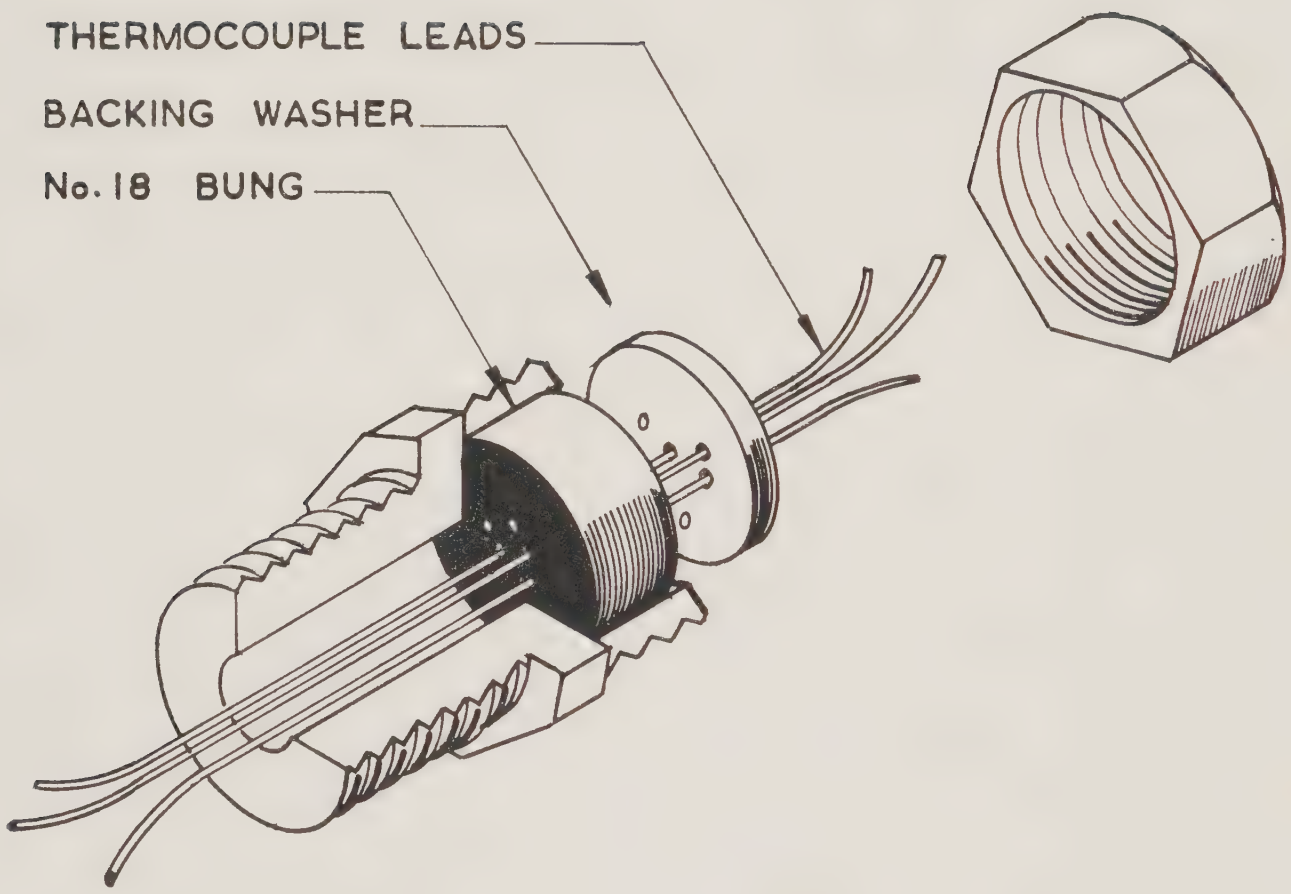
METHOD OF INTRODUCING THERMOCOUPLES
INTO STERILIZER CHAMBER



3/4" B.S.P. x 22 mm. COPPER COMPRESSION FITTING (YORKSHIRE 611LB 22mm x 3/4" M1).
SUITABLE FOR UP TO 12 TWIN CORE THERMOCOUPLES.

Figure A2.2

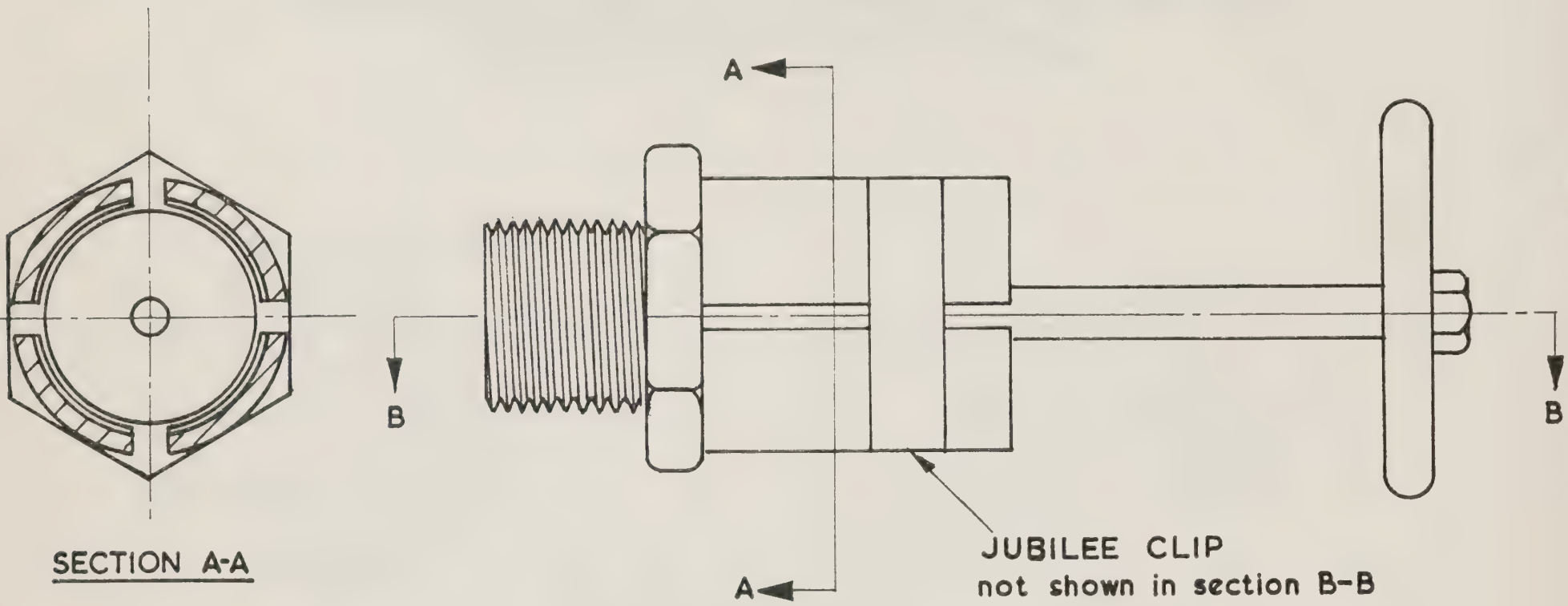
METHOD OF INTRODUCING THERMOCOUPLES INTO STERILIZER CHAMBER



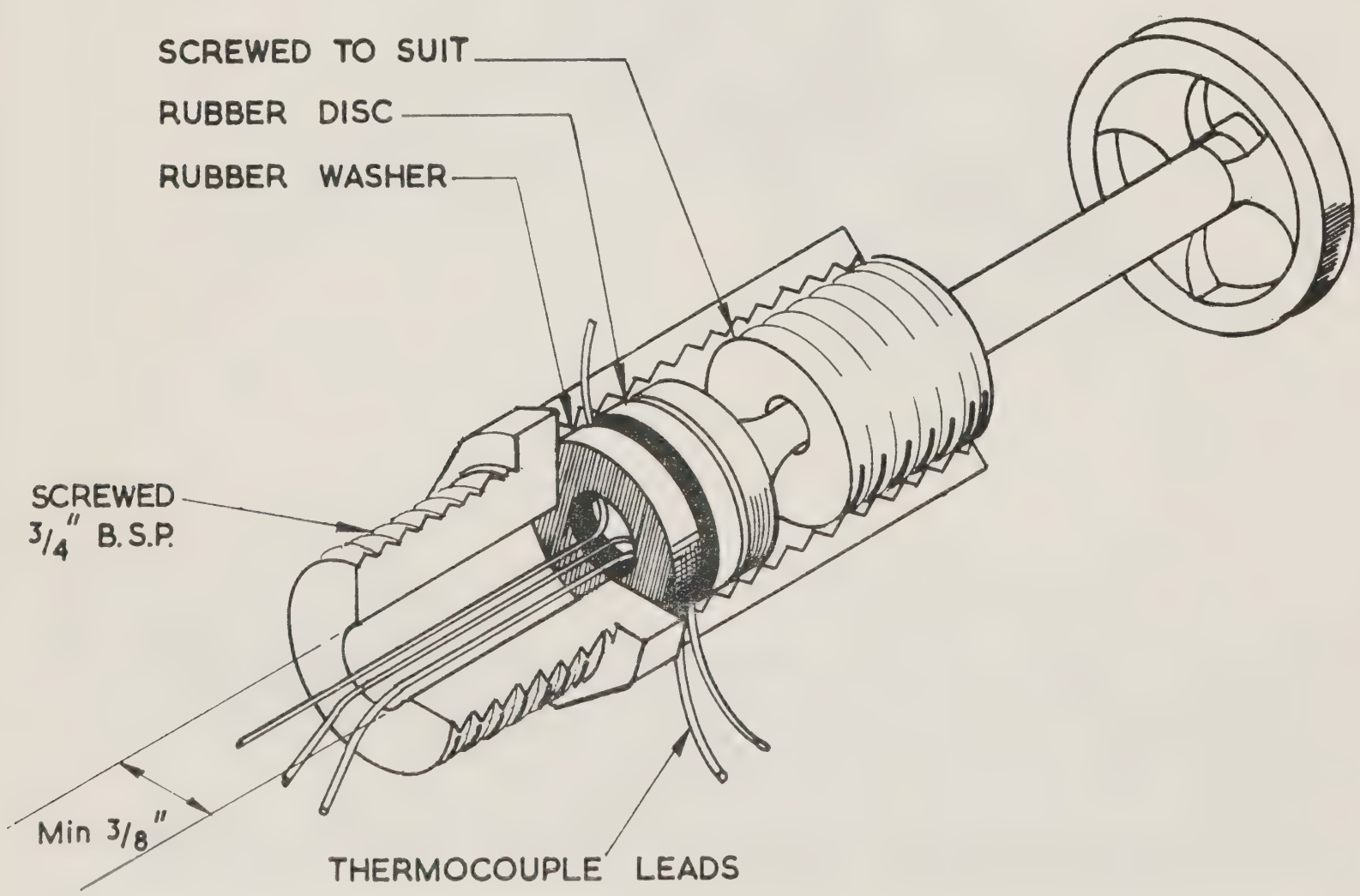
3/4" B.S.P. x 22mm COPPER COMPRESSION FITTING (YORKSHIRE 611 LB 22mm x 3/4" M.I.) FITTED WITH No. 18 RUBBER BUNG CUT TO LENGTH AND SUITABLE BACKING WASHER.
SUITABLE FOR UP TO 6 TWIN CORE THERMOCOUPLES.
FOR 12 THERMOCOUPLES USE TWO GLANDS ON A 'Y' BRANCH.

Figure A2.3

METHOD OF INTRODUCING THERMOCOUPLES INTO STERILIZER CHAMBER



SECTION A-A



SECTION B-B

SUITABLE FOR UP TO 12 THERMOCOUPLES OF EITHER TWIN OR SINGLE CORE WIRE

Appendix 3

Planning information

A3.1 Information given in this Appendix is intended as a general guide for initial planning purposes. There are wide variations between the actual dimensions, weights and service requirements of different makes of sterilizer. The actual requirements of the machines to be installed should be established before detailed planning is undertaken because they can differ widely from manufacturer to manufacturer for a given size of sterilizer.

A3.2 The provision of adequate clearance around machines, giving access for maintenance, is essential. Not less than the minimum clearance should be provided in all cases, although some manufacturers may claim that smaller clearances are permissible. The minimum clearance should be 900mm. around all parts to which access for routine maintenance is necessary (see Figures A3.1 and A3.2 and Table A3.1).

A3.3 Particular care should be taken to ensure that sufficient clearance is allowed for large items, such as vacuum pumps, to be withdrawn from the sterilizer frames.

A3.4 Attention is drawn to the need for adequate ventilation of the area near the sterilizers to remove the heat emitted. The figures in Table A3.2 are for guidance only.

A3.5 Service pipework, e.g. steam and water pipes, should not be installed over the top of a sterilizer but kept to a wall away from the sterilizer. The run-outs to individual sterilizers should be at high level. Additional head room may be required with this arrangement to permit removal of a sterilizer without disturbance of the fixed pipework.

A3.6 Some useful information in connection with the design of services for sterilizers is given in Table A3.3.

Minimum planning dimensions

A3.7 The following notes refer to Figure A3.1 and to Table A3.1 below.

a. Dimension B does not include the projecting parts associated with sideways sliding doors. In most cases such projections are confined to the front end of the machine and can be accommodated within the recommended dimension A without impeding access for maintenance.

b. The minimum working height required for maintenance is 2700 mm. above floor level.

c. The dimensions quoted are also applicable to free standing units if allowance is made for the casing.

Table A3.1 **Minimum planning dimensions for typical sizes of sterilizer**

Type of sterilizer	*Size mm.*	*Nominal capacity litres*	*Dimensions as Figure A3.1 mm.*					*Weight (total) kg*	*Portage for installation/ removal (nominal)*	
			A(d)	*B*	*C*	*D*	*Height*		*Minimum dimensions metres*	*Weight*(e) *kg*
Porous loads	660 dia. × 760(a)	280	900	1300	1000(b)	3000(b)	2600	2040	1·3 × 1·0 × 1·5	1000
	660 × 660 × 660	300	900	1100	1500	1000	2200	600–1500	2·0 × 1·0 × 1·5	600–1500
	910 × 660 × 660	400	900	1200–1400	1700	1000	2200	650–1800	1·9 × 1·0 × 1·7	650–1800
	910 × 660 × 990	600	900	1400	2100	1000	2200	1100–1800	2·0 × 1·5 × 2·2	1000–1800
	910 × 660 × 1320	800	900	1400	2100	1200	2200	1100–1600	1·8 × 1·4 × 2·0	950–1600
Bottled fluids	910 × 660 × 660	400	900	1200–1400	1700	1000	2100	650–1800	2·1 × 1·6 × 1·9	650–1650
	910 × 660 × 990	600	900	1900	1700	1000–1500(c)	2100	1100–2000	2·1 × 1·5 × 2·3	900–1900
	910 × 660 × 1320	800	900	1900	2400	1000–1500(c)	2100	1100–2100	2·1 × 1·5 × 2·6	950–2000
	910 × 660 × 1600	970	900	1600	2300	1000	1800	2540	2·0 × 1·2 × 2·4	
Unwrapped Instruments and unwrapped utensils	300 dia. × 500	35	600	690	900	900	1800	350	not normally broken down	
	510 dia. × 510	100	900	1000	1000	1000	1900	450		
	450 dia. × 760	130	900	1000	1500	1000	1800	400–700		
	510 dia. × 910	180	900	1000	1700	1000	2000	550		
	510 × 510 × 910	240	900	1000	1700	1000	1900	750		

NOTES TO TABLE A3.1

(a) The figures 660 dia. × 760 relate to vertical chamber machine to B.S.3970 (see Figure A3.2).

(b) Excluding tracks for containers for vertical chamber machine.

(c) This dimension includes width of compressor plus 600 mm. clearance between wall and sterilizer.

(d) Dimension "A" must include provision for a sliding door (where appropriate), typically chamber width plus 450mm.

(e) There may be considerable variation in weight, depending upon manufacturer.

d. Extra allowance must be made for built-in or free standing steam generators when these have to be provided in addition.

e. Spacing should be such that it is possible to replace any sterilizer without disturbing others in the same installation. In some cases this will entail an increase in dimension D.

f. The building and room access doors should be of a type and size which will permit passage of the equipment.

g. A single door will be required in the front panel if there is no other direct route between the plant room and the front of the sterilizer(s).

h. When sterilizers with vertical sliding doors are used, the height of the base of the chamber above finished floor level is usually higher than with machines having hinged or horizontally sliding doors.

j. Break tanks, as may be required by paragraph 7.22 of Chapter 7, are not shown in these drawings.

k. Fire compartmentation should be considered.

*Table A*3.2 **Heat emission for all types of sterilizer**

Size mm.	*Nominal capacity litres*	*Heat emission (average) to surroundings at 20°C (excluding emission from load)*		
		Heat emission to user space kW	*Heat emission to plant room kW*	*Total heat emission kW*
510 dia. × 510	100	0·5	1·5	2·0
450 dia. × 760	130	0·5	1·5	2·0
510 dia. × 910	180	0·5	2·0	2·5
510 × 510 × 910	240	0·5	2·5	3·0
660 × 660 × 660	300	0·5	3·0	3·5
910 × 660 × 660	400	1·0	3·5	4·5
910 × 660 × 990	600	1·0	4·5	5·5
910 × 660 × 1320	800	1·0	6·0	7·0
910 × 660 × 1600	970	1·0	7·5	8·5

NOTES TO TABLE A3.2

a. The figures include emission from pipework fitted to the sterilizer but do not allow for excessive lengths of steam pipe manifold.

b. The total heat emission given is the maximum which might be expected. The proportion of heat emitted to the user space varies with the type and make of machine. These figures should therefore be used as a guide only and the advice of the manufacturer should be sought.

c. The heat emission to the user space is given for a sterilizer with the door normally closed; if the door is left open for a significant time with the steam jacket pressurized, the heat emission to the user space will be considerably increased.

d. The heat emission to the user space is greatly reduced, and the heat emission to the plant room is correspondingly increased, if the sterilizer door is mounted behind the fascia panel.

Table A3.3 **Approximate service connection sizes and demands**

	Chamber size		*Steam*				*Condensate*			*Water*		*Power*	*Compressed air*			
								Drain							*Consumption*	
Type of sterilizer	*Dimensions H.W.L. mm.*	*Nominal capacity litres*	*Inlet size mm.*	*Peak flow kg./s.*	*Max. kg./ cycle*	*Safety Valve vent size mm. (typical)*	*Jacket size mm.*	*Size mm. (typical)*	*Max. flow litres/ min.*	*Inlet size mm. (typical)*	*Flow litres/ min.*	*Total electrical load kW.*	*Pressure bar*	*Inlet size mm. (typical)*	*Maximum flow rate at S.T.P. l./min.*	*used per cycle at S.T.P. litres*
Porous loads	660 × 660 × 660	300	25	0·08	20	28	15	42	25	22	20	3·0	6	15	50[a]	30[a]
	910 × 660 × 660	400	25	0·08	25	35	15	42	25	22	20	3·0	6	15	50–120[a]	30–200[a]
	910 × 660 × 990	600	25	0·08	30	35	15	42	25	22	20	3·0	6	15	50–120[a]	30–200[a]
	910 × 660 × 1320	800	25	max. 0·08	50	35	15	54	25	22	20	3·0	6	15	50–120[a]	30–200[a]
Bottled fluids	910 × 660 × 660	400	22	0·08	55	35		42	40	22	20	2–4	6	15	50–120	1700[b]
	910 × 660 × 990	600	22	0·08	65	35		42	40	22	20	2–4	6	15	50–120	1800[b]
	910 × 660 × 1320	800	22	0·08	80	35		42	40	22	20	2–4	6	15	50–120	2400[b]
	910 × 660 × 1600	970	22	0·08	130	35		42	40	22	20	2–4	6	15	50–120	3000[b]
Unwrapped instruments and unwrapped utensils	300 dia. × 500	35	22	0·03	3	22	15	25	20	22	20	1	—	—	—	—
	510 dia. × 510	100	22	0·03	10	22	15	42	30	22	20	1	—	—	—	—
	450 dia. × 760	130	22	0·03	10	22	15	42	30	22	20	1	—	—	—	—
	510 dia. × 910	180	22	0·03	13	28	15	42	45	22	27	1	—	—	—	—
	510 × 510 × 910	240	22	0·03	15	35	15	42	45	22	27	1	—	—	—	—

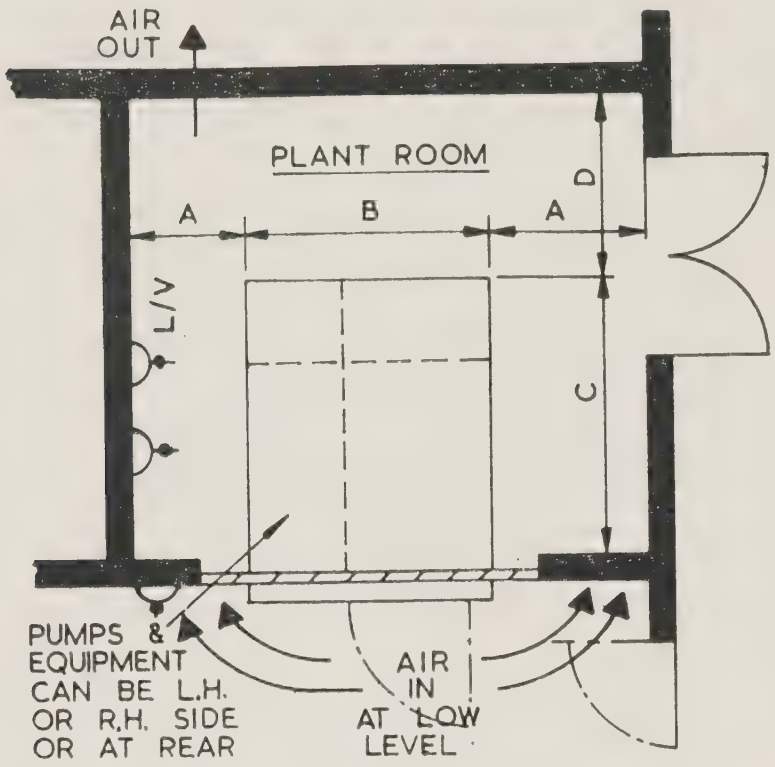
NOTES TO TABLE A3.3

(a) Consumption of compressed air when used to operate sliding door and pneumatic controls, which varies from manufacturer to manufacturer.

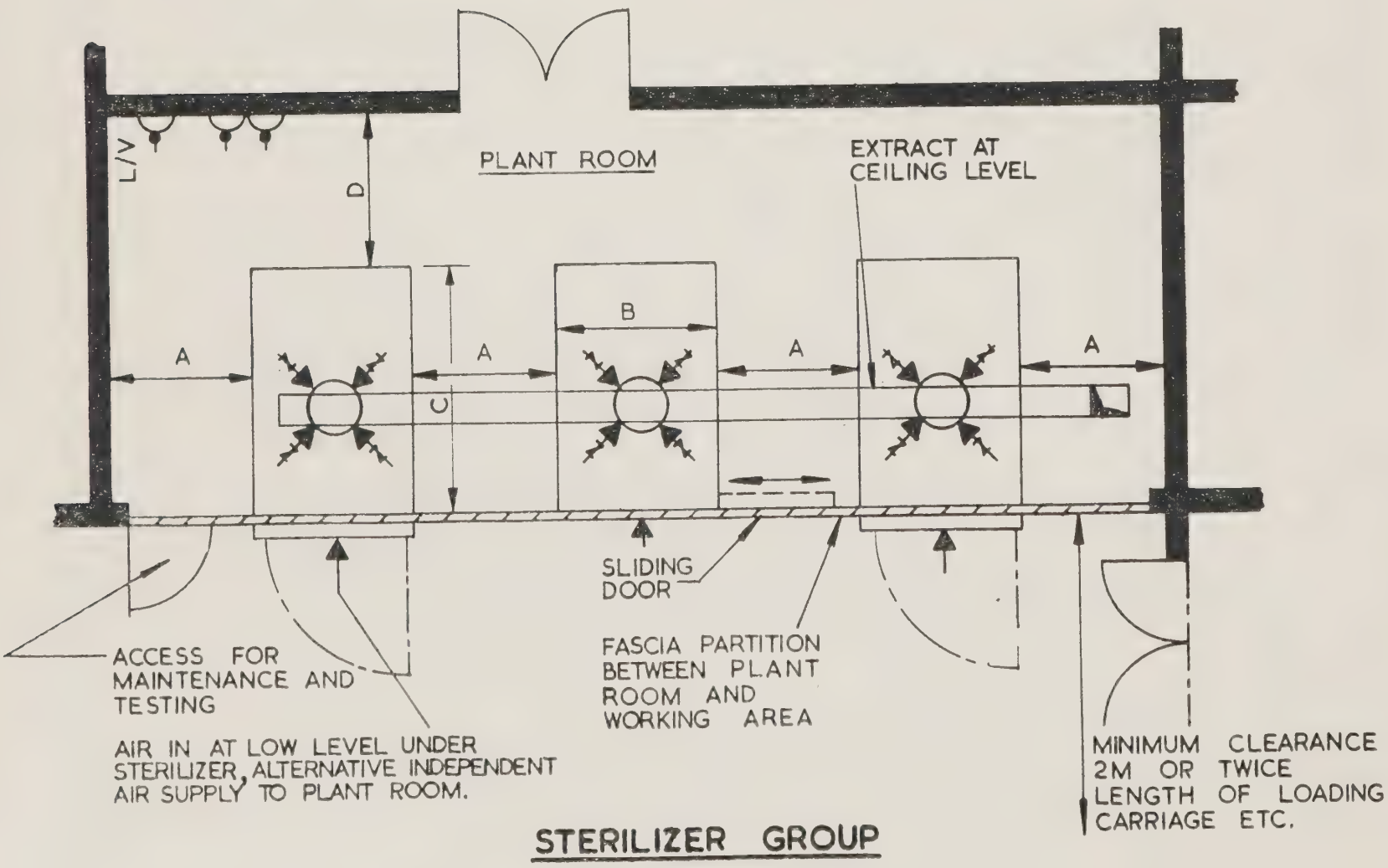
(b) Typical figures for machines with air ballast, sliding doors and pneumatic controls. If air ballasting is not used the air consumption will be the same as for porous load machines.

Figure A 3.1

TYPICAL PLANNING DIMENSIONS (not to scale)



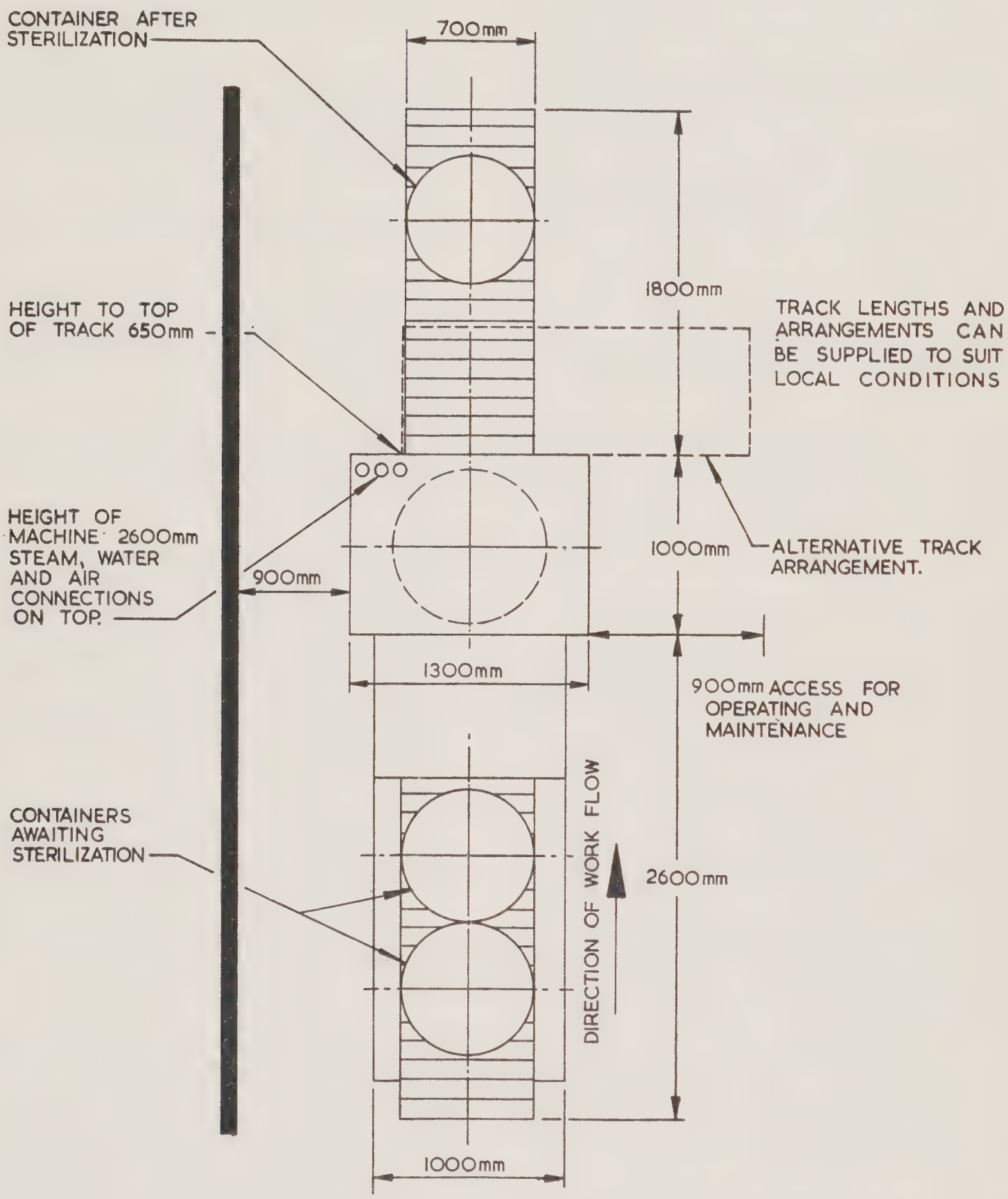
SINGLE STERILIZER



STERILIZER GROUP

Figure A 3.2

TYPICAL PLANNING DIMENSIONS FOR VERTICAL CHAMBER STERILIZER



CHAMBER

NOMINAL SIZE 660mm DIA x 760mm
NOMINAL CAPACITY 280 LITRES

CONTAINERS

NOMINAL SIZE 584mm DIA. x 760mm

Appendix 4

Commissioning, operation and maintenance of sterilizers

Introduction

A4.1 It is of utmost importance that all sterilizers are both effective in reaching the performance required for sterilization of loads and safe in operation.

A4.2 For assurance on these points responsibilities rest variously with the contractor who installs the machine, the Sterilizer Engineer, the Maintenance Engineer and the User. This Appendix identifies the duties and responsibilities of those concerned and describes the records which should be kept.

A4.3 When a new installation is to be handed over in full working order it is the contractor's duty to carry out the commissioning and to perform any demonstration which is necessary before the sterilizer may be accepted for use.

A4.4 A consultant microbiologist normally exercises clinical responsibility in a CSSD. It is current policy to recommend such oversight in any sterilizing unit.

A4.5 The duties of the Production Manager (or Production Pharmacist) and the Quality Controller are referred to in the context of sterilizers used for processing medicinal products.

Duties and responsibilities

The Sterilizer Engineer

A4.6 This person should have direct contact with the responsible Consultant Microbiologist and Principal Pharmacist for Quality Control in the Region. His duties in respect of all sterilizers are as follows:

a. advising on the choice of sterilizer in conjunction with the appropriate Health Authority staff and advising upon the services requirements;

b. advising on the contract details, including specification and drawings, test loads for commissioning and specifications in accordance with DHSS recommendations;

c. acting as Contract Supervising Officer (CSO) where so nominated, for the purpose of supervising the commissioning and acceptance tests in accordance with the contract requirements;

d. supervising or executing annual performance tests;

e. supervising or executing re-commissioning of a sterilizer after it has been withdrawn from service for the repair of a *serious* defect (see A4.44) or for the statutory two-yearly inspection of pressure vessels, or for modification or for change of duty;

f. examining the records of all other periodical tests, faults and unscheduled maintenance and advising, where necessary, on any action which appears to be required as a result;

g. certifying, after action as in d. or e. above, that the performance complies with that specified when the sterilizer was ordered and with any subsequently agreed variations, and approving, in agreement with the Microbiologist and the User, that the sterilizer is fit for service after such tests;

h. advising the Users upon the application of Master Temperature Record(s) (MTR(s)) to particular sterilizers/processes and the interpretation of such records (see A4.17);

j. advising upon the content of the maintenance schedules applicable to each sterilizer;

k. advising upon any sterilizer maintenance contract and on the general procedure to be adopted for calling the manufacturer's service engineers in emergencies;

l. confirming that proper engineering records arising from all commissioning and routine tests and checks are kept for each sterilizer;

NOTE: The form and contents of the records should be agreed between the Sterilizer Engineer, the Maintenance Engineer and the User. In the case of sterilizers used in the processing of medicinal products, the form of these records should also be agreed by both the Production Manager and the Quality Controller (see A4.9 and A4.10).

m. examining the Plant History Records and confirming that the agreed periodic testing and maintenance procedures have been undertaken;

n. advising the User in conjunction with the Contractor and the Maintenance Engineer upon the method of operating the sterilizer;

p. advising on which types of faults are to be considered as "serious" (see A4.44);

q. liaising with the Maintenance Engineer and the User to ensure the continuing satisfactory performance of the sterilizers, including engineering advice on specific problems, such as wet loads on porous load sterilizers.

The Maintenance Engineer

A4.7 The principal duties of this Engineer are as follows:

a. supervising maintenance tasks and tests, ensuring that faults are rectified, and seeking the advice or assistance of the Sterilizer Engineer where necessary;

NOTE: Maintenance will include cleaning the door joints and seals when these are not readily accessible to the operator.

b. responsibility for the upkeep of the Plant History Record and ensuring that records are kept on the approved test report forms;

c. executing quarterly and half yearly tests;

NOTE: These may, if mutually convenient, be undertaken by the Sterilizer Engineer.

d. co-operating with the Sterilizer Engineer in advising the User upon the method of operating the sterilizer;

e. liaising with the Sterilizer Engineer and the User to ensure the continuing satisfactory performance of the sterilizers;

NOTE: This will include approving, in advance, all procedures for calling in the manufacturer's service engineers in emergencies.

f. reviewing weekly, together with the User, the sterilizer performance and records for the previous week, comparing all Temperature Recorder Charts (TRCs) with the MTRs and investigating the cause of any abnormality;

g. holding all keys required for access to or control of the sterilizers, except those necessary for the operation of sterilizers, and duplicates of the keys necessary for the operation of sterilizers;

h. issuing Maintenance Certificates for each sterilizer at agreed intervals to the User.

The User

A4.8 The duties of the User are as follows:

a. reporting to the appropriate authority any breakdown of sterilizing plant which may affect the hospital service;

b. agreeing the operating procedure with the Sterilizer Engineer and Maintenance Engineer and liaising with them to ensure the continuing satisfactory performance of the sterilizers;

c. reporting to the Maintenance Engineer immediately there is any malfunction or suspected malfunction of a sterilizer, including:

(i) a failure to satisfy any approved routine test (such as the Bowie/Dick tape test for porous load sterilizers);

(ii) any accident or incident involving the machine;

(iii) any other feature of a sterilizer performance or behaviour which suggests that something may have happened to cause a change from the established normal behaviour of the machine;

d. co-operating with the Maintenance Engineer to ensure that sterilizers are made available for routine maintenance and periodic testing;

e. examining, at least daily, all TRCs and comparing them with the MTR for the sterilizer;

f. supervising the use of the Sterilizer Processing Log (see A4.46 to A4.50);

g. ensuring that the daily maintenance tasks are carried out by the Plant Operator (see e. above);

h. reviewing weekly, together with the Maintenance Engineer, the sterilizer performance and records for the previous week and comparing all TRCs with the MTRs, assisting as necessary in the investigation of the cause of any abnormality;

j. training the Plant Operators, with advice from the Sterilizer Engineer, in the correct use of the sterilizer, in the performance of the relevant tests and completion of the documentation;

k. holding those keys necessary for the operation of the sterilizers, as agreed with the Maintenance Engineer;

l. ensuring that sufficient forms, charts or record books, other than those held by engineers, are readily available since no machine may be operated without a record of performance being kept;

m. ensuring the satisfactory performance of the daily Bowie/Dick tape test for each porous load sterilizer, examining the result and authorising the use of the sterilizer if appropriate;

n. witnessing the leak rate test for each porous load sterilizer;

p. ensuring that he or she is in possession of a valid Maintenance Certificate for each sterilizer in use (see A4.24);

q. operation of the sterilizer, including the following:

(i) the normal housekeeping procedures and those daily maintenance tasks on the sterilizer

which are appropriate for a Plant Operator to carry out, such as cleaning the chamber, the chamber drain, the door joints and seals (where these are readily accessible to the operator), removing broken glass, labels and debris;

NOTE: These tasks should be scheduled by the User and agreed with the Sterilizer Engineer and the Maintenance Engineer.

(ii) exchanging charts on chart recorders and replenishing ink;

(iii) completing entries in the Sterilizer Processing Log and on TRCs;

Most of the duties in q. may be carried out by the Plant Operator under the supervision of the User.

r. ensuring that no sterilizer load is released for use until the relevant records have been checked and approved;

NOTE: These records will include the TRC when a recorder is fitted (see A4.13 a) and, where relevant, the appropriate entries in the Sterilizer Processing Log.

s. ensuring compliance with the procedure required in relation to the manufacture of pharmaceutical products.

The Production Manager and the Quality Controller

A4.9 In certain circumstances, such as the preparation of medicines controlled by the Medicines Act 1968, (7) (Health Service Circular (Interim Series) 128, April 1975 refers) (49), responsibilities lie with a Production Manager and a Quality Controller, as defined in the Guide to Good Pharmaceutical Manufacturing Practice (GPMP) (2). In such cases it is the duty of the former to be assured that the sterilization is both effective and safe, and the duty of the latter is to confirm these points by the means of quality audits. The Production Manager is usually the Pharmacist Manager in this situation. Support will be provided by the Sterilizer Engineer and Maintenance Engineer.

A4.10 For the purposes of this document, and in the case of machines processing medicinal products, any reference to the User is to be read as including the Production Manager, the Production Pharmacist and the Quality Controller, as appropriate.

Documentation and procedures

A4.11 In the context of this document a batch is defined as the contents of one load of a sterilizer.

A4.12 In order to comply with the necessary standards, such as the Medicines Act 1968 and the Health and Safety at Work, etc. Act 1974 (6), Health Authorities should keep records which provide assurance that the staff are performing their duties in a satisfactory manner. The attention of *engineering staff* is drawn to the procedures laid down in ESTMANCODE, Chapter II, Section 2 and in the associated Maintenance Manuals, PMG/12 and PMG/13 (10 and 11).

A4.13 The records to be kept vary for the type of sterilizer in use and should include:

a. commissioning data, including MTR charts which should be used as the standard for each batch;

NOTE: MTRs are not appropriate for machines, e.g. bowl and instrument sterilizers, for which temperature recorders are not a mandatory requirement. They are not necessary *for use by the operators of porous load sterilizers.*

b. Insurance Surveyor's report (not applicable to hot air sterilizers);

c. maintenance contract (where applicable);

d. maintenance certificate;

e. Plant History Record;

f. Sterilizer Processing Log for the following:

(i) sterilizers processing medicinal products (both steam and hot air sterilizers);

(ii) porous load sterilizers.

Commissioning data

A4.14 This data should be prepared and kept by the Sterilizer Engineer but, where appropriate, provision should be made in the contract documents for the test results to be prepared and provided by the contractor in a form suitable for incorporation in the commissioning data. A duplicate should be held by the Maintenance Engineer and kept in association with the Plant History Record.

A4.15 The sterilizer should be inspected and tested to establish whether it complies with the various requirements of the contract specification, including the relevant requirements of British Standards where these are called for in the specification. The data to be recorded should include:

a. the results of the inspection and/or test for each of the specification requirements;

b. such records as are necessary to demonstrate that the sterilizer is capable of performing satisfactorily with each batch size and type of load for which it was ordered;

NOTE: This will require the conduct of fully-instrumented tests but will not necessarily entail a separate test for every variation of loading condition. The tests which are necessary in each case should be determined as follows (see also A4.18):

(i) for sterilizers to be used for processing medicinal products, jointly by the Sterilizer Engineer, the Production Manager and the Quality Controller;

(ii) for all other sterilizers, by the Sterilizer Engineer in association with the Consultant Microbiologist;

c. records showing correlation between the performance of the instruments fitted on the sterilizer and the test instruments used for commissioning;

d. records showing correct functioning of the control equipment such as temperature controllers, timers, air detectors, load simulators, signal lights and indicators.

A4.16 The commissioning record should indicate satisfactory tests on the safety devices as appropriate, e.g. safety valves on jacket and chamber; door interlock preventing opening of door until temperature has fallen to a safe level; door interlock preventing entry of steam until door is properly secured; door interlock preventing unauthorized opening of the door after an unsatisfactory sterilization cycle.

NOTE: It may not be practical at present to equip some sterilizers with mechanical interlocks to prevent the doors or lids opening with the loads at an unsafe temperature or when the sterilization cycle has not been satisfactorily performed. These additional safety devices should be fitted as soon as it becomes practicable to do so; meanwhile operating instructions should be in terms to ensure safe operation.

A4.17 When correlation is accepted between the sterilizer TRC and the multi-channel commissioning recorder, the TRC is to be marked "MASTER TEMPERATURE RECORD" (MTR). Each MTR and corresponding chart from the multi-channel recorder is to be cross-referenced and endorsed as follows:

a. sterilizer plant reference number;

b. description of load (e.g. 500 ml. bottles of saline);

c. distribution pattern of load;

d. confirmation that all monitor bottles, or items of equipment in the load, reached the required temperature and were maintained at this temperature for the necessary time;

e. description and distribution pattern of other types and sizes of load, if any, for which the MTR is to be accepted as valid;

f. when the load comprises bottled fluids, the point during the cycle at which the load temperature had fallen to 80°C and the temperature interlock on the door opening mechanism was released;

g. signature of Sterilizer Engineer and date;

h. signature of User and date.

A4.18 A sufficient number and variety of MTRs should be prepared, so that for each loading condition (that is, for each batch type and size and each type of equipment to be sterilized) there is a suitable MTR available. In many cases the design of the sterilizer and/or the nature of the items to be sterilized will enable *worst case* loading conditions to be established or predicted with reasonable certainty, and thus allow one MTR to be used for several loading conditions. Particular care is necessary with respect to certain products, such as some solutions, which are subject to decomposition when heated. In these cases, the shape of the MTR must be such that it not only ensures certainty of sterilization but also it does not permit the product to be exposed to high temperatures for so long that unacceptable degradation occurs. The number of MTRs which are necessary in each case and the particular loading condition(s) for which each MTR is suitable should be determined as follows:

a. for sterilizers to be used for processing medicinal products, jointly by the Sterilizer Engineer, the Production Manager and the Quality Controller;

b. for hot air sterilizers not processing medicinal products, jointly by the Sterilizer Engineer and the User;

c. for all other sterilizers, by the Sterilizer Engineer.

A4.19 A copy of each MTR for all machines processing medicinal products and for hot air sterilizers must be supplied for daily reference by the User and should be kept with the Sterilizer Processing Log. Ideally it should be reproduced in transparent form, so that it can be laid over the TRC for comparison purposes.

A4.20 When it is accepted that the sterilizer has been correctly set up and is working satisfactorily, a record should be made of all the significant details of a normal cycle under automatic control. The cycle should be performed with a standard test load in the chamber, details of which should be recorded. In the case of porous loads machines a standard single pack test load of the type used for Bowie/Dick and thermocouple tests should be used. Observations should also be made of details of each stage and sub-stage of the cycle such as the time taken, the number of pulses, temperatures, pressure and levels of vacuum at all significant points

during the cycle, e.g. at the end of each stage or sub-stage.

A4.21 The commissioning data for porous loads machines should include records of performance tests on the vacuum system as follows:

a. the maximum level of vacuum achieved during the leak rate test;

b. the maximum acceptable leak rate specified for the machine, against which it should be tested;

c. the actual leak rate measured during the leak rate test;

d. the vacuum level(s) achieved during the vacuum stage(s) should be included amongst the data to be recorded during the cycle as required by paragraph A4.20.

Insurance Surveyor's report

A4.22 This should be obtained by the Maintenance Engineer at statutory intervals.

Maintenance contract (where applicable)

A4.23 A copy of any sterilizer maintenance contract should be held by the Maintenance Engineer.

Maintenance certificate

A4.24 The Maintenance Engineer should certify to the User, at agreed fixed intervals, that the necessary schedules of maintenance tasks have been satisfactorily completed. A detailed entry should have been made in the Plant History Record. Provided it is compiled and endorsed in a suitable manner and kept where the User has free access to it, the Plant History Record may be used to perform the function of the Maintenance Certificate. A typical Maintenance Certificate is shown in Appendix 15.

Plant History Record[a] (including Record of Maintenance and Periodic Tests)

A4.25 The Maintenance Engineer should be responsible for this document but, where appropriate, it may be combined with the Sterilizer Processing Log; in such cases the two separate parts of the combined document should be clearly identified.

A4.26 The document should carry the plant reference number for the individual sterilizer and the date of installation and commissioning. It should contain records of all performance tests, irregularities in performance and modifications to the sterilizer. It should also record all maintenance work, both scheduled and unscheduled, and show that the examinations, tests and checks have been carried out as cited in the sterilizing plant sections of ESTMANCODE Maintenance Manuals PMG/12 and PMG/13 (10 and 11). It should be noted, however, that the maintenance schedules in these manuals may need to be modified to suit a particular sterilizer, in accordance with the maintenance schedules recommended by the manufacturer or as the result of experience. Such variations should be noted in the Plant History Record.

A4.27 The Maintenance Engineer should sign and date, at least weekly, all entries relating to maintenance, both scheduled and unscheduled.

A4.28 The User should countersign weekly that he has seen the entries, indicate whether he is satisfied with them and comment where appropriate. In the case of sterilizers processing medicinal products, both the Production Manager and the Quality Controller should examine, sign and date the record weekly, or at intervals to be agreed locally.

A4.29 Records for entry in the Plant History Record should include those detailed in the following paragraphs.

Data for setting and testing

A4.30 All the data necessary for setting and testing the sterilizer should be summarized and presented in a convenient form for reference, including that derived from manufacturing information and from commissioning and subsequent performance tests.

Weekly record

A4.31 This should include as appropriate to the type of sterilizer:

a. records of tests carried out on the automatic process control system. These records should be made during a normal cycle under automatic control, the chamber being loaded as it was for the commissioning test at A4.17 and should include:

(i) records of indicating thermometer, TRC and pressure gauge readings under "steady state" conditions during the "sterilizing" stage;

(ii) records of details of each stage and sub-stage of the cycle such as the time taken, number of pulses, temperatures, pressures and levels of vacuum at all significant points during the cycle, such as the change from each stage or sub-stage to the next;

[a] This document may be used in lieu of the Plant History Record, PMG/8 (50), detailed in ESTMANCODE. If it is so used, the details of the costs of maintenance works may also be recorded therein.

(iii) record of the results of investigation into the reasons for any deviation from their normal values of any of the parameters recorded;

b. confirmation that all TRCs have been examined and by whom;

c. leak rate test results, including the level of vacuum achieved, as well as the rate of leakage into the chamber;

d. a statement of the maintenance tasks carried out during each week and whether these have been completed satisfactorily;

NOTE: The tasks need not be detailed in full, identification of the relevant task schedules by, for example, *Weekly* or *Quarterly* will suffice, exceptions only being detailed.

e. confirmation that the door seal has been examined and is satisfactory;

f. confirmation that the door safety devices have been tested and are satisfactory.

Quarterly record

A4.32 Records of quarterly tests which, subject to the discretion of the Sterilizer Engineer, should repeat the commissioning tests, except that they may be made with an instrument with a minimum of 3 channels instead of a 12-channel chart recorder as used during commissioning.

A4.33 In the case of fluids sterilizers one batch type and size only need be tested but the various batch types and sizes should be tested in rotation at subsequent quarterly tests.

A4.34 The record should include the results of the air detector performance test for porous load sterilizers and any load simulator test for sealed fluids sterilizers.

A4.35 There are no quarterly tests on hot air sterilizers.

Half-yearly record (for hot air sterilizers only)

A4.36 Records of tests on hot air sterilizers which, subject to the discretion of the Sterilizer Engineer, should repeat the Production Load Test.

Yearly record

A4.37 Records of annual performance tests which, subject to the discretion of the Sterilizer Engineer, should repeat the commissioning tests.

Records as required

A4.38 A record of faults and unscheduled maintenance should be kept (see A4.42–A4.44).

A4.39 A record of modifications to the sterilizer should be kept (see A4.6 e).

A4.40 A record of re-commissioning tests should be kept which should repeat some or all of the commissioning tests. The particular tests which are appropriate in each case should be determined as in A4.18. In the case of sterilizers processing sealed fluids for which MTRs have previously been established, re-commissioning tests need only be performed for two batch/contents sizes.[a] The two test loads should be distinctly dissimilar, e.g. 1 litre bottles and 20 ml. bottles (or the largest and smallest bottle sizes regularly processed). The following circumstances will indicate the need for re-commissioning tests to be carried out:

a. when a machine has been moved and re-installed at a new site (not applicable to portable "bench top" machines);

b. when a machine has been withdrawn from service for the repair of a "serious" defect (see A4.44);

c. when a machine has been subjected to the statutory two-yearly inspection of pressure vessels;

d. when a machine has been overhauled or modified;

e. when there is a change to a cycle or type of load for which no suitable MTR is available, such as the introduction of a new loading pattern, a new type of load, a change in container volume or a change in batch size;

f. when there is a significant change in the pattern of the TRC from that of the MTR;

NOTE: If there is any doubt about whether a change is significant, the advice of the Sterilizer Engineer should be sought. In the case of machines processing sealed fluids, any change in the time of stage 1 (heat up) or stage 2 (sterilizing) of the sterilizer cycle by more than 3 minutes from that shown on the MTR should be regarded as significant.

g. when there is a demand for re-commissioning by an Authorised Inspectorate or Licensing Authority;

h. when the Sterilizer Engineer considers re-commissioning to be necessary.

NOTE: The advice of the Sterilizer Engineer about whether re-commissioning is necessary should be sought when there is any replacement of a component or alteration or adjustment affecting the steam pressure, operational pressure or

(a) A complete range of new MTRs will be required if the two batch tests reveal significant changes in the MTRs.

temperature setting or cycle timing (other than permitted selection by the User) or when there has been a replacement or adjustment affecting the continuous discharge rate of the chamber drain, where this is possible.

A4.41 Each record as in A4.32, A4.36, A4.37, A4.39 and A4.40 should include a statement of the fitness for use and be signed and dated as follows:

a. for annual tests, for re-commissioning tests and for modifications, by the Sterilizer Engineer;

b. for quarterly and half-yearly tests between the annual tests, by either the Sterilizer Engineer or the Maintenance Engineer;

c. these records should be countersigned and dated by the User, who should indicate whether he is satisfied with them and comment if appropriate.

NOTE: In the case of sterilizers processing medicinal products, both the Production Manager and the Quality Controller should countersign the record.

Fault procedures and records of faults

A4.42 Any fault found by the Sterilizer Engineer, the Maintenance Engineer or the User should be recorded in the Plant History Record.

A4.43 If the Sterilizer Engineer or the Maintenance Engineer finds a fault he should inform the User forthwith.

A4.44 If a serious fault occurs, the sterilizer should be withdrawn from service and should not be used for production of sterile materials until it has been approved for re-use jointly by the Sterilizer Engineer or Maintenance Engineer and the User. The Sterilizer Engineer should advise, for each type of sterilizer, which types of faults are to be considered as *serious*. The list should include all faults which may result in failure to sterilize or danger to personnel or damage to the product. In the case of faults not classified as serious the machine may be taken back into service immediately after rectification of the fault and on satisfactory completion of the tests listed as *Weekly Tests* in Appendix 6 (29).

A4.45 Details of remedial action and subsequent performance checks should also be recorded. These entries should be signed and dated by the Maintenance Engineer or, if appropriate, by the Sterilizer Engineer, and should be countersigned by the User before the machine is returned to service.

Sterilizer Processing Log: general requirements

A4.46 The User should be responsible for this document, but where appropriate it may be combined with the Plant History Record; in such cases the two separate parts of the combined document should be clearly identified.

A4.47 The entries as in A4.49 or A4.50 below should be made, where relevant, by the User or nominated Plant Operator for each load sterilized, and the log should be countersigned weekly by the Maintenance Engineer to indicate that he has seen it.

A4.48 At the commencement of each working day the readings on the cycle counter should be recorded in the Processing Log (or in the Plant History Record where a Processing Log is not required). The thermometer and pressure gauge reading during the sterilizing stage of the first cycle in the day should be similarly recorded.

A4.49 The Sterilizer Processing Log for medicinal products, whether the machine is of the steam or hot air type, should include:

a. product title and batch size, or description of load;

b. batch number;

c. sterilizer cycle number;

d. indicating thermometer, TRC and pressure gauge readings at "steady state" during the "sterilizing" stage;

e. time at sterilizing temperature (determined from TRC);

NOTE: It is the duty of the Production Manager to ensure that a. to e. are properly completed for each batch.

f. an entry in respect of each batch, signed and dated by the Production Manager, stating whether the TRC matches the MTR for the batch or product;

g. details as in a. to f. above need not be recorded separately if they are already recorded in a Batch Manufacturing Record: the Sterilizer Engineer and the Maintenance Engineer require access to these records.

h. an entry, signed and dated by the Quality Controller at least weekly, confirming that he has examined the entries for the week in both the Plant History Record and the Sterilizer Processing Log or Batch Manufacturing Record and stating whether he is satisfied with them;

j. an entry, signed and dated by the Maintenance Engineer at least weekly, to acknowledge that he has seen the entries;

k. the TRC, marked to link unambiguously with the sterilizer serial number and, for each cycle, the product title, batch size or description of load, batch number and sterilizer cycle number.

NOTE: The TRC should be signed and dated either by the Production Manager or by the Quality Controller to confirm that it matches the MTR and that the loading pattern was the same as that specified on the MTR. A separate chart for each cycle is preferred.

A4.50 The Sterilizer Processing Log for porous loads should include:

a. the daily Bowie/Dick tape test result;
NOTE: The test sheet should be marked to show the sterilizer serial number, sterilizer cycle number, date and signature of the User. The sheet should also be marked to identify it with the corresponding entry in the Processing Log.

b. an entry signed by the User stating whether the TRC for each load is satisfactory;

NOTE: The TRCs should each be marked to identify the sterilizer, cycle number(s) and date. A separate chart for each cycle is not required. The record should be clearly marked to show any TRC relating to any unsatisfactory cycle. The record must include details of any load which is automatically rejected as non-sterile.

c. an entry signed by the User to confirm that he has seen all records made in the Plant History Record during the week and indicating whether he is satisfied with them;

NOTE: The entries should include the results of the weekly temperature and automatic control test, including vacuum levels.

d. an entry, signed and dated by the Maintenance Engineer, to confirm that he has examined the details in the log at least weekly, and that the daily Bowie/Dick TRCs compare satisfactorily with the temperature record obtained during commissioning.

Retention of records

A4.51 For pharmaceutical products, records should be kept as required by the GPMP, or, if not specified, records relating to the process, including the Sterilizer Processing Log, TRCs and Bowie/Dick tape test sheets, should be kept for at least twelve months.

A4.52 Records relating to the plant, including commissioning data, MTRs, Insurance Surveyors' Reports and Plant History Records should be kept throughout the life of each sterilizer.

Appendix 5

Check-list of pre-commissioning procedures

Checks of adequacy of engineering services and of general engineering performance of sterilizer

A5.1 The sterilizer has been provided and installed in accordance with the specification and drawings.

A5.2 Tests have been satisfactorily completed on all the services provided by the Services Contractor or Sub-Contractor.

A5.3 The electrical equipment on the sterilizer has been provided, installed, connected and tested and is acceptable.

A5.4 The noise and vibration levels during operation are acceptable.

A5.5 There are no leaks of steam, water, air or effluent at any temperature or pressure within the working range.

A5.6 All supports, bases and fixings are rigid and secure, and without imposed strain from pipework connections.

A5.7 When the sterilizer appears to be functioning in a proper manner there is no evidence of interference with the performance of other equipment connected to the same services or of unsatisfactory operation of existing drainage services.

Tests of performance of sterilizer mechanical and electrical function (including safety devices) under working conditions

A5.8 Steam, water and air supply pressures during full cycle of operation are satisfactory.

A5.9 Drains effectively remove effluent when all plant in the vicinity, including the sterilizer, is connected.

A5.10 There is no adverse effect of the full operation of all services on other connected plant in the vicinity.

A5.11 Safety devices ensure the following:

a. doors are locked before the admission of steam;

b. doors cannot be unlocked when under internal pressure greater than 0·2 bar (3 psi) gauge;

c. steam valve closes on failure of power supply (simulated);

d. chamber is vented to atmosphere during opening of door via the door opening and before the securing mechanism is fully released.

A5.12 The interlock between manual and automatic control allows only one system to be used at one time.

A5.13 Operation of an automatically controlled sterilizer ensures it meets the specification requirements as set out in the manufacturer's operating details.

A5.14 Operation of a manually controlled sterilizer ensures it meets the specification requirements as set out in the manufacturer's operating details.

A5.15 During each stage of the operating cycle, the controls react correctly and safely under the following conditions:

a. low steam pressure;

b. low water pressure;

c. incorrect vacuum;

d. simulated power failure.

A5.16 Operation and readings of all instruments appear satisfactory, including return to zero.[a]

A5.17 Calibration of all instrumentation and controllers is satisfactory.

A5.18 Temperature of exposed surfaces of the sterilizer, including all valve handles and door operating gear does not exceed an ambient temperature by more than 20°C.

A5.19 Loading trolleys or other aids are effective in use.

---

[a] This may not be achievable with combined pressure and vacuum gauges.

Appendix 6

Summary of sterilizer performance tests

Undertaken by	*Sterilizer Engineer*	*User*	*Maintenance Engineer*	*Maintenance Engineer (and/or Sterilizer Engineer by local arrangement)*	*Maintenance Engineer (and/or Sterilizer Engineer by local arrangement)*	*Sterilizer Engineer*	*Sterilizer Engineer and "Competent Person"*
Frequency / Type of sterilizer	When commissioning and recommissioning[a,b,c]	Daily[d]	Weekly[b,e]	Quarterly[e]	Half-yearly[e]	Yearly[e]	2-yearly, or yearly in certain cases [e,f]
Porous loads	(1) Perform weekly tests, see Appendices 4, 7, 8 and 9 (2) Thermocouple test (using 3 thermocouples), see Appendix 7 (3) Air detector tests, see Appendix 10	Bowie/Dick tape test, see Appendix 8	(1) Temperature and automatic process control test, see Appendix 7 (2) Bowie/Dick tape test, see Appendix 8 (3) Leak rate test, see Appendix 9	(1) Repeat weekly tests (2) Thermocouple test (using 2 or 3 thermocouples), see Appendix 7 (3) Air detector FUNCTION test, see Appendix 10	Repeat quarterly tests	(1) Repeat quarterly tests (2) Air detector PERFORMANCE test, see Appendix 10	Statutory inspection by Competent Person, in addition to yearly performance test(s)
Fluids	(1) Perform weekly test, see Appendices 4 and 11 (2) Thermocouple test (using 11 or 12 thermocouples), see Appendix 11	NIL	Temperature and automatic process control test, see Appendix 11	(1) Repeat weekly test (2) Thermocouple test (using 3 thermocouples), see Appendix 11	Repeat quarterly tests	(1) Repeat weekly tests (2) Thermocouple test (using 11 or 12 thermocouples), see Appendix 11	
Unwrapped instruments and utensils	(1) Perform weekly test, see Appendices 4 and 12 (2) Thermocouple test (using 3 thermocouples), see Appendix 12	NIL	Temperature and automatic process control test, see Appendix 12	Thermocouple test (using 2 or 3 thermocouples), see Appendix 12	Repeat quarterly test	Repeat quarterly test	
Low temperature steam and formaldehyde	To be covered in Addendum to HTM No. 10						
Laboratory	To be covered in Addendum to HTM No. 10 Test programme not available. As a guide, tests no less stringent and no less frequent than those for the types shown above should be undertaken for the appropriate processes.						
Ethylene oxide	To be covered in Addendum to HTM No. 10. For this process micro-biological test pieces must be included with each load.						
Hot air sterilizers	Thermocouple test(s) (usually using 12 thermocouples), see Appendices 4 and 13	NIL	NIL	NIL	Thermocouple test(s) (using 3 thermocouples), see Appendix 13	Thermocouple test(s) (usually using 12 thermocouples), see Appendix 13	NIL

(a) Tests on completion of installation of a machine by a contractor will be carried out by the contractor under the supervision of the Sterilizer Engineer.

(b) These tests must also be carried out after unscheduled maintenance under certain circumstances. (See Appendix 4, paragraphs A4.40 and A4.44.)

(c) The Sterilizer Engineer has some discretion on the test conditions to be applied. (See Appendix 4, paragraphs A4.15, A4.18, A4.32–A4.35, A4.36, A4.38–A4.40.)

(d) Readings of temperature and pressure during sterilizing stage of first daily cycle (not the "warm-up" cycle) should be recorded in Processing Log (see Appendix 4, paragraph A4.48). Cycle counter reading should be similarly recorded. Temperature and pressure at steady state are to be recorded in Processing Log FOR EACH BATCH OF MEDICINAL PRODUCTS.

(e) These tests should be performed in association with and on completion of PPM tasks.

(f) Inspection by "Competent Person" (normally an insurance company engineer) applies to all steam pressure vessels, i.e. sterilizer chambers and associated steam generators, condensers and compressed air receivers. In most cases two-yearly inspection is applicable, but "annual" inspection is required for steam generators and for those sterilizers in which the steam is generated within the chamber, e.g. by immersion heaters. The actual statutory periods are 26 months and 14 months, respectively. Factory Forms F55 (51) and F55A (52), available from HMSO, should be used for the 14-monthly inspection and Form F58 (53) for the 26-monthly inspection.

Appendix 7

Performance tests for porous load sterilizers

General

A7.1 The tests required are those referred to in Appendix 4, the records of which are required for day-to-day production control purposes. They are as follows:

a. Bowie/Dick tape test (see Appendix 8).

b. Leak rate test (see Appendix 9).

c. Temperature and automatic process control test.

d. Quarterly test.

e. Yearly, commissioning and re-commissioning tests.

f. Air detector performance test (see Appendix 10).

A7.2 For all these tests, except b., the sterilizer should be loaded with a test casket or pack containing about 30 freshly laundered and aired towels as for the Bowie/Dick tape test. They should be carried out after a *warming-up* cycle has been performed (or otherwise in accordance with manufacturer's instructions).

A7.3 The Bowie/Dick tape test and the leak rate test are complementary.

A7.4 Machines which satisfactorily pass these tests are deemed to be capable of sterilizing all porous loads. Packaging and loading and operating procedures must be devised which will enable the sterilizer to process "difficult" loads in a satisfactory manner, e.g. by extending the drying time.

Weekly temperature and automatic process control test

A7.5 This test may be performed simultaneously with the daily Bowie/Dick tape test where this is possible without contravening any of the essential test conditions.

A7.6 The sterilizer should be operated under automatic control and the complete test cycle should be observed. At least three readings of chamber temperature and pressure should be taken from the sterilizer instruments at equal time intervals during the sterilization hold time. A record should be made in the Plant History Record of all these observations, and this should also include details of each stage or sub-stage of the cycle, such as time taken, number of pulses, temperature, pressure and levels of vacuum at all significant points in the cycle, e.g. at the change from each stage or sub-stage.

A7.7 The test should be considered satisfactory if all the following requirements are met.

a. The TRC agrees satisfactorily with the MTR.

NOTE: This is not the MTR referred to for sterilizers processing medicinal products which are required for production control purposes for checking individual batches, but the record obtained during commissioning which is retained for checking performance.

b. The measured parameters are consistent with previously recorded test results.

c. The engineer observing the test does not detect any mechanical or other anomaly.

d. On completion of the test, the towels which comprise the test pack, or the contents of the casket, are sensibly dry.

A7.8 A satisfactory Bowie/Dick tape test is required (see Appendix 8).

Common requirements for quarterly, yearly, commissioning and re-commissioning tests

A7.9 Each quarterly, yearly, commissioning and re-commissioning test requires temperature measurements to be recorded by separate thermometric equipment, using a minimum of two thermocouples during TWO separate performance tests, i.e. a small load test and a full load test.

A7.10 For each of these performance tests, one thermocouple should be placed in the chamber drain, within 100 mm. of the exit from the chamber, and another at the geometric centre of the towels comprising the test pack, the wires being carefully arranged to prevent steam tracking along them.

A7.11 The first test should be performed with the single test pack in the chamber.

A7.12 For the second test the chamber should be fully loaded with a supply of packs of laundered and aired cotton fabrics sufficient to fill the sterilizer to a density of about 160 kg/m.^{3} (10 lb./ft.^{3}) including the test pack, which may be placed at any convenient position within the chamber.

A7.13 The temperature and automatic process control test should be carried out in association with the first test, and observations should be made as described and recorded. It may be necessary to perform the leak rate test without the single test pack in the chamber.

A7.14 The second test should only be carried out on satisfactory completion of the first test.

Appendix 7 continued

A7.15 The tests should be considered satisfactory if all the following requirements are met.

a. The temperature in the test pack is within the limits of $134 \pm {}^{4}_{0}$°C during a continuous period of 3 minutes of Stage 2.

b. During the last 2 minutes of this sterilizing *hold* period, the temperature in the test pack and drain should be coincident within the accuracy limits of the instrumentation.

c. The duration of Stage 2 does not exceed 6 minutes (stage as defined in B.S.3970, Part 1).

d. The cycle is completed in not more than 30 minutes.

In the case of machines which are set to operate with an extended drying time, the drying stage only must be re-set for the purposes of this, so that the cycle is completed in not more than 30 minutes.

e. The packs are sensibly dry.

Yearly, commissioning and re-commissioning tests

A7.16 The minimum number of thermocouples which should normally be used is three—one in the chamber drain, one in the centre of the test pack and the other, for detecting superheat, fixed about 50 mm. above the test pack.

NOTE: The thermocouple in the chamber drain should be in contact with condensate at the phase boundary condition. This may sometimes require deeper insertion than the recommended 100 mm.

A7.17 The geometric centre of the test pack may not always be the most appropriate location for the "load" thermocouple and additional thermocouples may be placed in the test pack, e.g. in the upper and lower halves; the temperature indicated by any one of the load thermocouples must be coincident with that indicated by the thermocouple in the chamber drain during the last 2 minutes of the sterilizing hold period, within the accuracy limits of the instrumentation.

A7.18 The limits for superheating are given in Appendix 1.

Appendix 8

The Bowie/Dick tape test for porous load sterilizers[a]

Introduction

A8.1 There will be even and rapid penetration of steam into the load in a porous load sterilizer only if sufficient air and non-condensable gases are removed from the chamber and load before steam is admitted during the "sterilizing" stage. If air and non-condensable gases are not removed from the chamber and load or from the steam supply they may become trapped within the load. This would prevent penetration of that part of the load by steam and consequently sterilizing conditions may not be achieved.

A8.2 A method of demonstrating that even and rapid penetration by steam has occurred is by the use of thermometric equipment, with thermocouples appropriately placed within the chamber and load. Such a test is described as a performance specification test in B.S.3970.

A8.3 This method of testing is not practicable on a daily basis, and it was for this reason that the Bowie/Dick tape test was developed. The Bowie/Dick tape test on its own *does not* confirm that sterilizing conditions have been achieved in the load. The test *does* prove whether or not steam penetration of the test pack has been even and rapid and that air or other non-condensable gases were not present and have not entered the test pack. Consequently daily assurance that a porous load sterilizer is functioning correctly is achieved by a combination of tests, records and observations of which the Bowie/Dick tape test is only a part. The other tests, records and observations which must be made regularly are considered elsewhere in this document, but the vital evidence which can be gathered from each is summarized in the table below. From this table it can be seen that no single test or observation gives conclusive evidence that the sterilizer is processing the load correctly. *A satisfactory result from all the tests and observations is necessary for such assurance.*

The technical process on which the test is based

A8.4 An adhesive tape, which is printed with a chemical substance, is fixed in the shape of a St. Andrew's cross to a piece of suitable paper and this test sheet is placed at the centre of a stack of towels (the test pack). The chemical substance shows a colour change related to time and temperature when exposed to phase boundary steam. The depth of colour change is dependent on the time of exposure and the temperature and moisture. The indicator is much less sensitive to dry heat; exposure to air at 134°C for 3 minutes will cause no discernible colour change, whereas exposure to phase boundary steam at 134°C for 3 minutes will cause a marked colour change. To obtain an optimum colour change for interpretation, the Bowie/Dick tape test must *not* be run for longer than $3\frac{1}{2}$ minutes at 134–138°C. If this period of $3\frac{1}{2}$ minutes is exceeded the tape may undergo such a colour change as to make it practically impossible to detect colour variations along the tape in a *fail* condition.

A8.5 Steam will penetrate rapidly and completely and the tape will show a uniform colour change if all the air is removed. If all the air is not removed before the steam is admitted for the sterilizing stage the air will

(a) Bowie, J. H., Kelsey, J. C., Thompson, G. R. (1963). The Bowie and Dick autoclave tape test, *Lancet*, i, 586. (54)

Test, record or observation	*Evidence*
1. Temperature record chart for each load	a. Whether the correct number and profile of pre-sterilization pulses have been obtained. b. Whether the correct temperature has been maintained in the chamber for the necessary time.
2. Indicating thermometer	a. Whether the correct temperature has been obtained in the chamber. b. By comparison of 1 and 2, during steady state conditions whether either instrument is faulty.
3. Air detector function	Whether air and other non-condensable gases are present within a sample of the chamber atmosphere.
4. Bowie/Dick tape test	Whether there has been even and rapid penetration of steam into the test load at the commencement of the sterilizing stage. (NOT necessarily whether a sterilizing temperature/time relationship has been achieved in the load.)
5. Leak rate test	Whether the evacuated chamber is adequately sealed.

collect within the pack as a *bubble*. The colour of the tape in the region of the *bubble* will be paler than elsewhere along its length, because of the lower temperature and/or reduced moisture level. This will be observed when the paper with the tape cross is examined.

A8.6 The test pack is chosen since it represents the maximum density of porous load which a sterilizer conforming to B.S.3970, Part I, is designed to process, i.e. about 160 kg. of fabric material per cubic metre of chamber space. The more air there is to remove the more exacting will be the test—that is why the test pack is used by itself in an otherwise empty chamber.

A8.7 The Bowie/Dick tape test was originally applied to high vacuum sterilizers, in which air removal was effected by a single evacuation of the chamber. Most modern porous load sterilizers employ a pulsing or multistage process to remove air from the chamber, and the relevance of the Bowie/Dick tape test to this type of sterilizer is sometimes queried.

A8.8 It must be emphasized that the test is still valid in these circumstances because the time/temperature characteristics of the steam pulses do not significantly change the colour of the test tape. There is, therefore, no significant danger of obtaining a spurious result unless the air removal stage is unusually long. If the air removal stage exceeds about 15 minutes, the advice of the Sterilizer Engineer should be sought on the method of performing the Bowie/Dick test, so as to ensure its validity.

Material used in the test

A8.9 The test is invalid if materials of the correct quality are not used. The requirements are:

a. *Towels*

These must be huckaback towels conforming to B.S.1781 for Class TL6 (55) (or TL5 if available). More Class TL6 (56) towels are required to make a standard pack than when Class TL5 towels are used. After purchase and before use the towels must be thoroughly washed to remove the *dressing*. If this is not done the towels become hardened and their ability to entrap air is diminished.

When towels are washed they should not be starched, ironed or calendered since this also diminishes the ability of the towels to entrap air. Towels in use should be washed at least once a week.

Towels should be unfolded and hung out for at least an hour between tests so that their humidity is stabilized. The use of slightly damp or compressed towels can result in the test giving a *pass* result when it should have been a failure. Towels which have become excessively de-hydrated may lead to super-heating in the pack, which might also produce misleading results.

b. *Tape*

The only tapes currently recommended are DRG 2538 and 3M's No. 1222 autoclave tapes. Both these tapes have a manufacturing date stamped on the core and only tapes bearing this stamp should be used. Under normal storage conditions the tape has a 12-month shelf life. Tape which is more than 12 months old should not be used for the Bowie/Dick tape test, but is perfectly satisfactory as a packaging tape/process indicator.

The tape should be stored in cool, dry conditions away from direct sunlight and artificial light.

The exact colour change shown by a processed tape will vary between different rolls and batches of tape, consequently tape from the same roll should be used for each test.

c. *Paper*

The use of waxed, greaseproof or heavily glazed art papers will seriously impair the accuracy of the test. The test sheet may be conveniently standardized on an A4 sheet of white, woodfree, duplicator paper (80 g/m^2).

Making up the test pack

A8.10 Each towel should be folded in half, three times, to provide eight thicknesses, each with an area of 300 mm. × 225 mm., and placed one above the other to form a stack about 270 mm. high (Figure A8.1). The exact number of towels needed will depend on how often they have been used, but 25 to 36 may be needed. A piece of paper to which autoclave tape has been applied in the form of a St. Andrew's cross is placed in the middle of the stack. The format suggested is shown in Figure A8.2. It is not necessary to add more tape than is indicated, since the use of additional tape may impair the interpretation of the text. The stack may be placed in a dressings casket (such as that described in B.S.3281 (57)) or in a box made of cardboard or metal which is not airtight. If preferred, the stack can be wrapped in fabric or paper, or it can be secured with tape. Whichever method is used the towels must stay in position when the test pack is handled. The towels must be laid quite flat with no ridges. When more than 36 towels are needed to give the required height it indicates that the towels are worn and should be replaced.

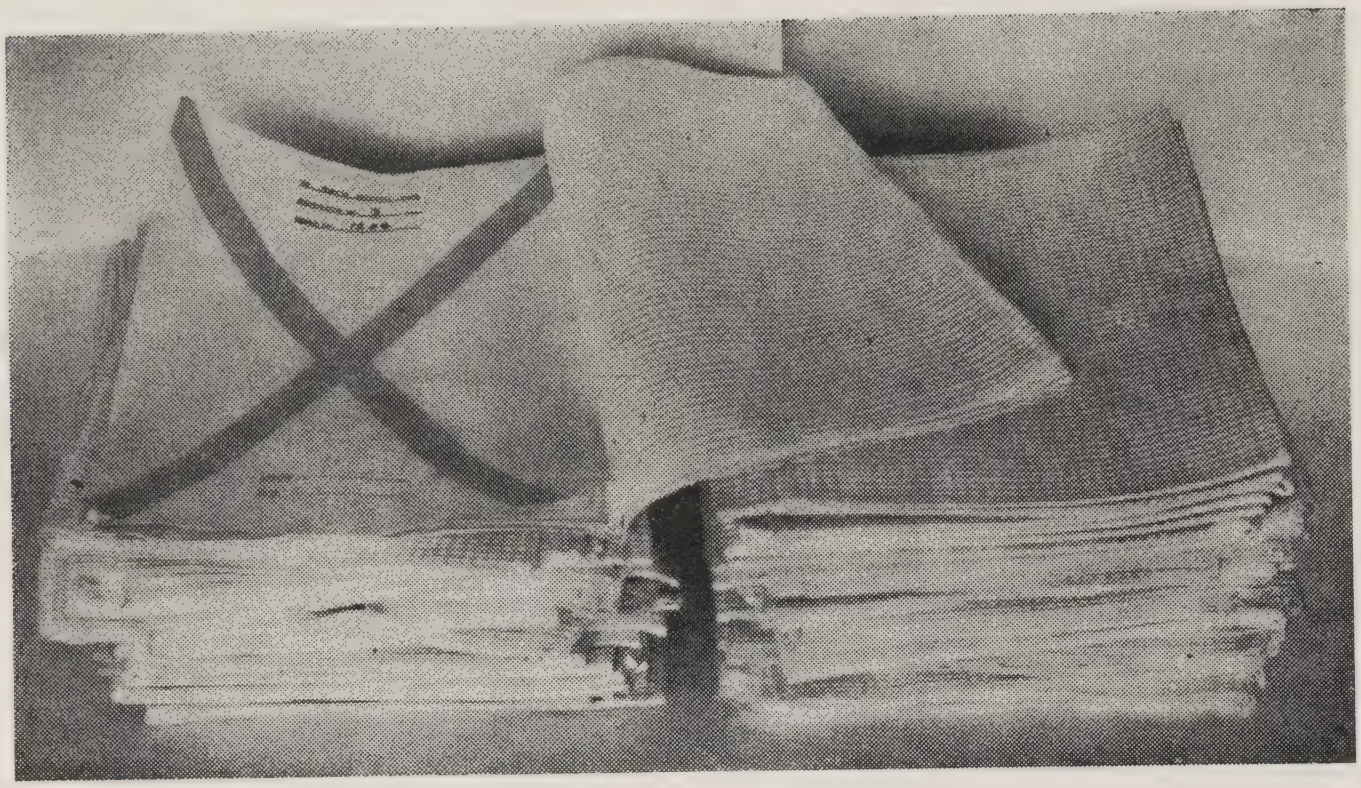


Figure A8.1 **Towels ready for test**

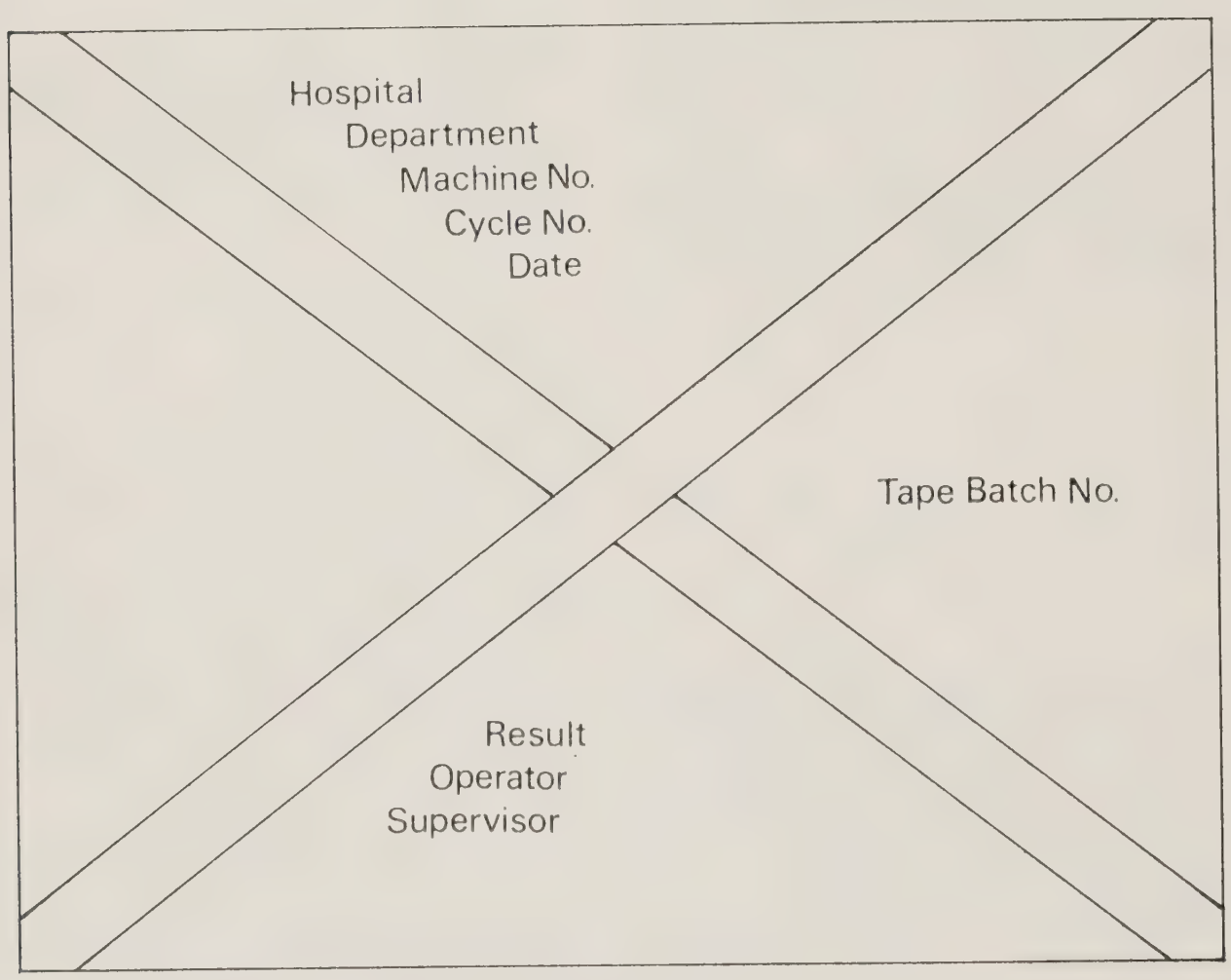


Figure A8.2

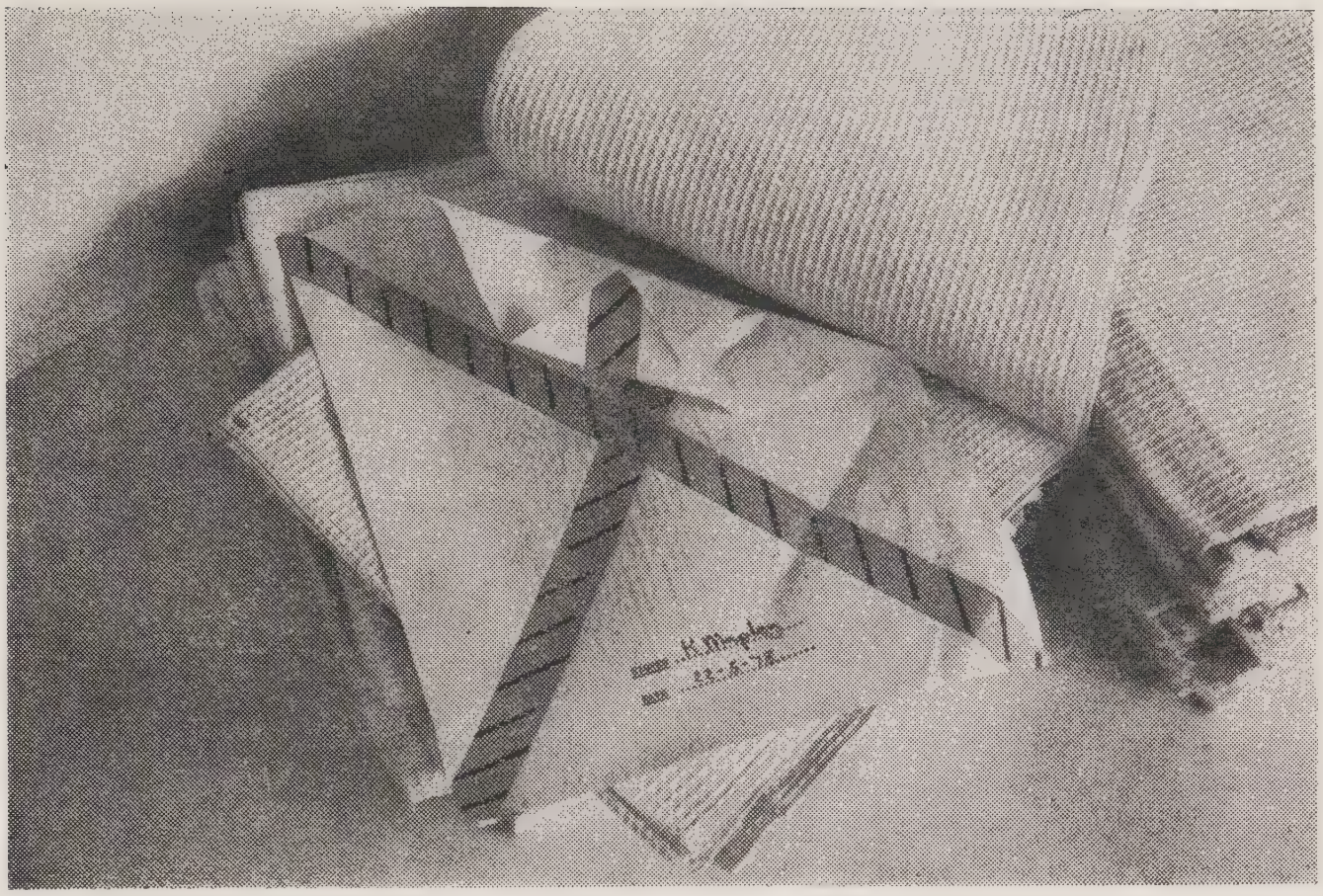


Figure A8.3 **A satisfactory test result**

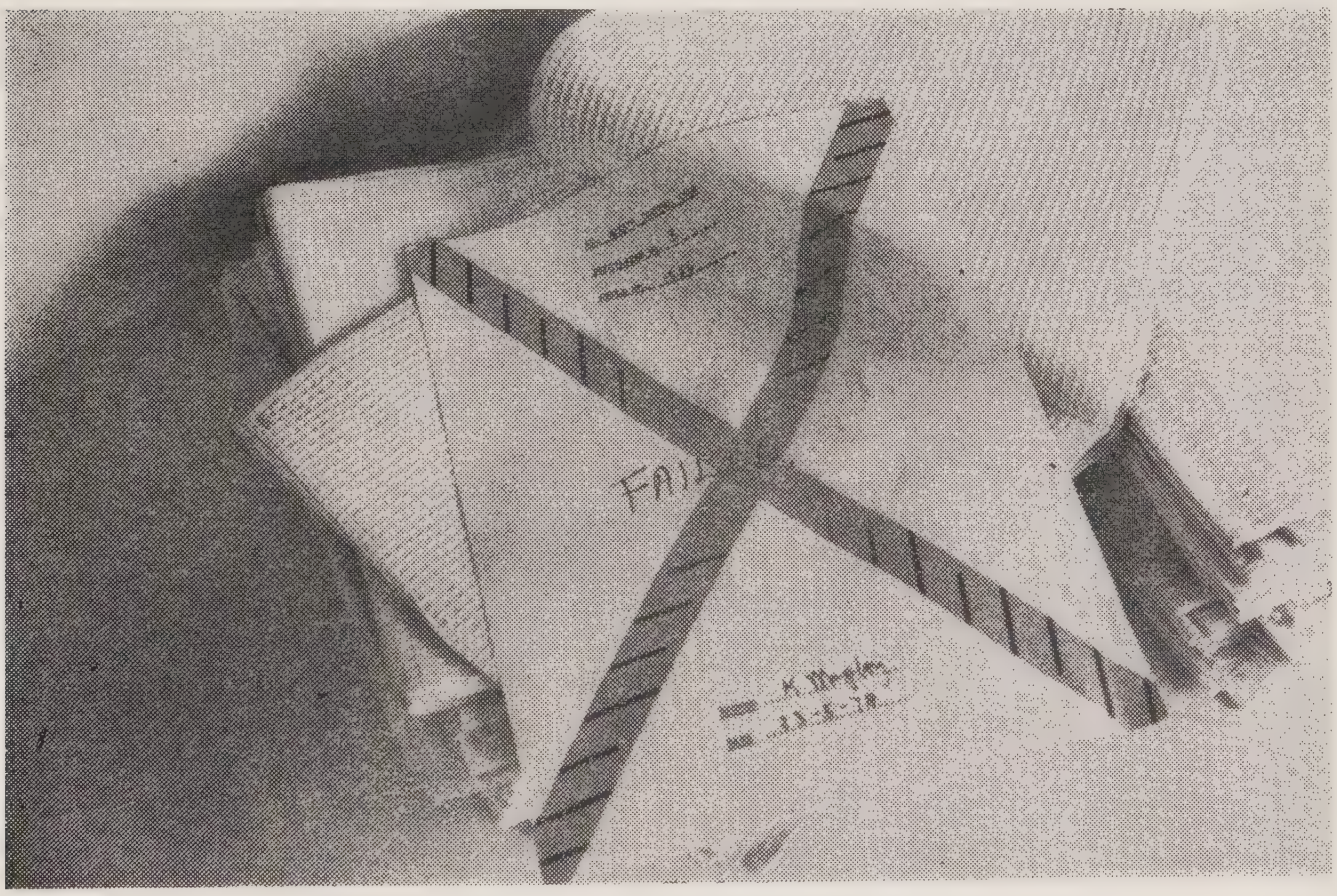


Figure A8.4 **A failed test result**

Note: Because of difficulties with photographic reproduction it is only possible to show a gross failure. Indications of a failure are usually more subtle and can only be detected by folding the paper in the manner shown in Figure A8.3 and comparing the central and outer parts of the tape.

Performing the test

A8.11 The test pack must be placed on the longitudinal centre line of the chamber, 100 mm. from any door and approximately 100 mm. above the chamber base of an otherwise empty sterilizer, with the towels lying horizontally. It must be subjected to a standard sterilizing cycle. The *holding* or *sterilizing* time must not be more than $3\frac{1}{2}$ minutes if a temperature of 134°C to 138°C is being used.

A8.12 The test should normally be carried out under automatic control, but if the automatic control is set for a longer holding time than $3\frac{1}{2}$ minutes the stage must be cut short, for the purposes of the test, by using the manual control. If there is any doubt about how to do this the Maintenance Engineer should be asked for advice. Machines should be modified where necessary, with the advice of the Sterilizer Engineer, so that the test can be done under automatic control.

A8.13 It is important that a *warming up* cycle is performed on the machine before the test run is started, since the effectiveness of air removal may depend on all parts of the sterilizer being at working temperature. A satisfactory sterilizer may give a fail result if this is not done.

Reading the test

A8.14 When interpreting the result of the test it is important to place the corner of the test sheet adjacent to its centre in order to make a direct comparison of the colour indicator density. For the test result to be accepted as a *pass*, the same colour change must occur along the length of the tape (see Figure A8.3) and if there are any discernible differences the test should be recorded as *failed* and the paper should be marked accordingly. Where there is a large area of unchanged indicator at the centre of the sheet this is indicative of a gross failure (see Figure A8.4).

Action following the test

A8.15 The paper from each test should have been marked as indicated above and be kept for reference for 12 months, together with the associated chart from the temperature chart recorder (see Appendix 4, paragraphs A4.49k, A4.50b and A4.52).

A8.16 It is important to realize that if a sterilizer fails to pass the Bowie/Dick tape test it cannot be made safe merely by increasing the holding time until a uniform colour change is produced. Such a sterilizer is in urgent need of skilled attention.

A8.17 A satisfactory test result does not indicate the ability of the machine to sterilize. It only indicates that the steam will evenly penetrate a load. Satisfactory temperature and pressure readings during the sterilizing stage and an acceptable temperature record chart are required as assurance of sterility.

A8.18 An unsatisfactory test result indicates that the machine must not be used until the fault has been rectified.

A8.19 If the sterilizer does not indicate *Non-Sterile* when a failed Bowie/Dick tape test is obtained, this implies that the air detector is not working properly. The machine should not be returned to service until the air detector has been overhauled and the machine performance checked by means of independent thermometric equipment (see Appendix 4).

Appendix 9

Leak rate test for porous load sterilizers

A9.1 This test is applicable only to porous load sterilizers, on which it is performed at least weekly.

A9.2 There are two reasons why leakage of air into the chamber at a rate greater than that specified (see A9.9) is unacceptable. They are as follows:

a. the presence of air prevents proper penetration of the load by steam and thus inhibits sterilization;

b. air leaking into the chamber at the end of the sterilization stage will not have passed through the bacteria-retentive filter and therefore there is a potential risk of re-contaminating the load.

A9.3 The leak rate test involves the drawing of a vacuum in the chamber, followed by the closure of all valves leading to the chamber, stopping the means of drawing the vacuum and observation of the chamber pressure for a timed period. The manufacturer's instructions should be followed in the conduct of the test; in case of doubt the advice of the Sterilizer Engineer should be sought. During the leak rate test it is desirable to record the maximum level of vacuum attained, as this gives an indication of the performance capability of the air removal system.

A9.4 The test requires the use of an absolute pressure gauge. These gauges are usually calibrated to cover the range 0–100 mm./Hg. absolute or 0–150 mbar absolute.

A9.5 The leak rate test must be carried out when the machine is at normal working temperature. On machines where the test is performed at the end of an air removal stage this will necessitate a previous complete cycle to warm the machine. On machines where the test is performed during the drying stage of a completed cycle a previous full cycle is not necessary.

A9.6 Most modern sterilizers have an automatic *leak test* position, operated usually by a key switch on the fascia of the sterilizer. During the test this switch is turned to the *leak test* position, the cycle is commenced with an empty chamber and at the appropriate time (usually in the drying stage) the chamber is automatically isolated and the vacuum pump stopped. The vacuum level achieved at this point should be recorded. A period of approximately 5 minutes should be allowed after the pump has stopped for the full closure of valves and for stabilization of conditions in the chamber. The absolute pressure gauge reading should then be recorded and a period of 10 minutes timed (preferably with a stop watch). After this period has elapsed the absolute pressure gauge reading should again be recorded.

A9.7 Experience indicates that a leak rate equivalent to a rate of change in pressure of 1·3 mbar/minute (1 mm. Hg./minute) over a period of 10 minutes after stabilization is the maximum which should normally be permitted. Leak rates in excess of this level tend to create inconsistencies in sterilizer performance.

A9.8 The *leak rate test* and the *Bowie/Dick tape test* are complementary tests. A sterilizer which fails to meet the requirements of either of these tests must not be used until the fault(s) has been rectified and the sterilizer satisfies both of these tests.

A9.9 Considerable care and knowledge must be applied in the interpretation of the results of leak tests. On a typical test the absolute pressure may rise by 20 mm. Hg. or more (e.g. 25 mbar) in the first few minutes of the test, due to the evaporation of moisture remaining in the chamber and connecting pipework. Such a result does not necessarily indicate a leak. If there is an initial rise in pressure, due to this evaporation (5 minutes is usually allowed) the test should be continued for a further period of 10 minutes, and during this further period the rise in absolute pressure should be noted.

A9.10 It is recommended that those sterilizers which are neither technically obsolete nor reaching the end of their useful working life and are not fitted with an automatic *leak test* position should be modified to provide this facility. Until the modification has been completed, it may be necessary to ensure that certain hand-operated valves are closed during the tests.

Appendix 10

Air detector tests for porous load sterilizers

A10.1 An air detector is fitted as part of the control system of a porous load sterilizer. Its function is to monitor the conditions within the chamber to determine whether or not the air present is sufficient to impair the sterilizing process.

NOTE: Some air detectors monitor part and some the whole of the sterilizing stage; others monitor only the start of the sterilization *hold* stage or some other part of the air removal stage.

A10.2 A correctly adjusted air detector will contribute to a minimum standard of product security; it should not be regarded as an alternative to effective maintenance.

A10.3 The air detector does not monitor the residual air in the load. The air detector and the Bowie/Dick tape test are complementary. The air detector should be tested for FUNCTION only when consistent Bowie/Dick failures occur.

A10.4 A leak rate test should always precede an air detector test, to establish whether or not the leak rate of the sterilizer is within the acceptable limits. (The air detector tests may require the leak rate test PROCEDURE to be used.)

A10.5 There are two air detector tests. These are:

a. *Air detector function test*

(i) This test should be undertaken when the air detector performance is suspect. It does not require separate instrumentation other than a simple metering device (e.g. a small valve by means of which air may be introduced into the chamber) used in conjunction with the absolute pressure gauge fitted to the sterilizer.

(ii) The test entails establishing that the air detector will fail a cycle before the maximum leak rate specified by the manufacturer is introduced. (The maximum leak rate should be equal to, or less than, that leak rate established during commissioning, which resulted in the temperature measured at the centre of the Bowie/Dick test pack being 2°C lower than the temperature measured in the drain line during the last 3 minutes of the 6 minutes permitted to Stage 2.)

(iii) In practice it is usual to quote the maximum and minimum of a range of leak rates over which the air detector may be expected to cause indication of a failure to sterilize. These are commonly, pass at 3·0 m. bar/minute and fail at 6·0 m. bar/minute.

b. *Air detector performance test*

(i) This test should be performed during commissioning and also when the air detector has failed a FUNCTION test. The test requires the use of separate thermometric equipment with thermocouples, one inserted in the geometric centre of a Bowie/Dick test pack, in an otherwise empty chamber, and one in the chamber drain, and in conjunction with either the metering device referred to for the FUNCTION test.

(ii) This test entails establishing that the air detector will fail a cycle before the temperature measured at the centre of the test pack differs by more than 2°C from that in the drain during the last 3 minutes of the 6 minutes permitted to Stage 2.

Features common to both tests

A10.6 It is necessary to introduce air into the chamber at a controlled rate whilst one or more cycles are performed under automatic control. Because the different types of air detector may operate at different parts of the cycle, it is usually necessary to regulate the introduction of air into the chamber during a leak rate test, by observing the absolute pressure gauge fitted to the sterilizer. The regulating device should be screwed into an entry boss in the front lower part of the chamber.

Particular features of the FUNCTION test

A10.7 This test is performed with an empty chamber, using the regulating device. During a leak rate test, or otherwise as indicated by the manufacturer, the regulating device should be opened to allow sufficient air *in-leakage* to result in the maximum change of pressure over a given time interval specified by the manufacturer. The sterilizer should then be operated under automatic control, with the regulating device open at this setting. The air detector should then fail the cycle.

A10.8 The sterilizer should be checked at regulating device settings which result in both the maximum and minimum leak rate, if the manufacturer specifies a range of leak rates over which the air detector should operate, e.g. the "2 mm./minute" and "4 mm./minute" leak rates.

A10.9 If the air detector fails to operate in accordance with the specified parameters it should be adjusted in accordance with the manufacturer's instructions by personnel who are competent to undertake the work, using separate thermometric equipment, and adopting the PERFORMANCE test procedure.

Particular features of the PERFORMANCE test

A10.10 The sterilizer should be operated under automatic control, and the regulating device should be opened up over successive cycles until the 2°C temperature difference between the pack and drain line is reached. The air detector should fail the cycle either when or before this temperature difference is reached during the last 3 minutes of the 6 minutes permitted to Stage 2.

NOTE: Certain designs of air detector have particular characteristics which permit other methods of testing, e.g. where the device is sufficiently sensitive to residual air, omission of part of the air removal stage may have the same effect as a deliberately induced leak. In this case the efficiency of the air removal stage should be progressively down-graded until the 2°C depression is obtained.

A10.11 When adjustment of the air detector is necessary it should be carried out in accordance with the manufacturer's recommendations and only by personnel competent to undertake the work.

Comparison between Function Test and Performance Test

A10.12 During commissioning or re-commissioning tests the *leak rate* required to result in the 2°C differential should be measured and noted. This should be equal to or greater than the maximum leak rate specified by the manufacturer.

NOTES:

a. Any change in the leak rate necessary to cause the 2°C differential should be recorded in the Plant History Record, and the new value should be used for subsequent FUNCTION tests.

b. The leak rate measured in these tests will automatically include any permissible leak rate for a particular machine because the air entering via the regulating valve will be additional to any leaking in at the door seal, etc. Satisfactory air tightness of the chamber, demonstrated by a satisfactory leak rate test as described in Appendix 9, is essential to ensure the repeatability and thus the validity of these tests. The regulated part of the total leakage in these tests should be as large as possible. If possible the door should be left closed between consecutive test runs, because it may cause variations between the normal leak rate and the regulated leak introduced in the tests.

Appendix 11

Performance tests for sterilizers for fluids in sealed containers (Bottled fluids sterilizers)

General

A11.1 The tests required are those referred to in Appendix 4, the records of which are required for batch and day-to-day production control purposes and apply to sterilizers processing sealed bottles. They are as follows:

a. weekly temperature and automatic process control test;

b. quarterly test;

c. yearly, commissioning and re-commissioning tests.

A11.2 For all these tests the bottles should be filled with fluid to a level which should normally not exceed 80 per cent of their capacity. The temperature of all the filled bottles should be similar before the test is commenced.

Weekly temperature and automatic process control test

A11.3 One standard batch should be used for the performance of this weekly test. It should be typically representative of all batches normally processed and one for which a MTR has been established during commissioning (see Appendix 4, paragraph A4.17). Ideally, the specification of the test batch should be identical to that of a commonly processed batch type, so that the test observations may be made during a normal production run. If the test is satisfactory the batch may be passed into stock.

A11.4 The sterilizer should be operated under automatic control and the complete test cycle should be observed. At least four readings of chamber temperature and pressure should be taken from the sterilizer instruments at equal time intervals during the sterilization hold time. Observations should also be made of temperatures and pressures at other significant points of the cycle, and the duration of the various stages and sub-stages of the cycle. A record should be made in the Plant History Record of all these observations.

A11.5 The test should be considered satisfactory if all the following results are observed:

a. the temperature record chart agrees satisfactorily with the appropriate MTR;

b. the measured parameters are consistent with previously recorded test results;

c. the engineer observing the test does not detect any mechanical or other anomaly;

d. the interlock, which prevents opening of the door whilst the load temperature exceeds 80°C, is not released at a point in the cycle significantly before that shown on the MTR.

NOTE: In those cases where it is not physically possible to observe operation of the interlock it will be necessary to attempt to operate the door mechanism as if to open the door. Very great care must be exercised to ensure that, if the door mechanism moves at all, it is moved only just sufficiently to establish whether the interlock is engaged or released. The mechanism must not be allowed to move far enough for the door to be inadvertently opened if the interlock has released before the safe temperature had been reached.

Common requirements for quarterly, yearly, commissioning and re-commissioning tests

A11.6 Each quarterly, yearly, commissioning and re-commissioning test requires temperature measurements to be recorded by separate thermometric equipment, using thermocouples in test bottles and in the chamber drain. Each thermocouple in a bottle should be on the vertical axis, between 20 mm. and 30 mm. above the base of the bottle.

A11.7 The thermocouple in the chamber drain should be within approximately 100 mm. of the exit from the chamber. In the case of a small sterilizer having no drain, this thermocouple should be inserted in an appropriate position within the chamber steam space, but below the bottom of the lowest bottle.

NOTE: The thermocouple in the chamber drain should be in contact with condensate at the phase boundary condition. This may sometimes require deeper insertion than the recommended 100 mm.

A11.8 The test recorder chart should be marked to show the start and finish of the sterilization hold time, details describing the test load, the distribution pattern of the load within the chamber, and the point at which the door may be opened (i.e. release of the door interlock mechanism so that the door may be opened).

A11.9 A temperature and automatic process control test should be carried out in association with these tests, and observations should be made as described under *Weekly Test* and recorded.

A11.10 The tests should be considered satisfactory if all the following results are observed:

a. the thermocouples and fluid remain sealed in the test bottles throughout the cycle;

b. not more than 1 or 1 per cent[a] (whichever is the greater) of the containers comprising the load has broken;

[a] The breakage rate for new unprocessed bottles may exceed this.

c. the temperatures measured are within the permissible limits for sterilization throughout the appropriate sterilization hold time, which are:

Sterilizing Temperature °C		*Time (Mins.)*
115	+ 3 — 0	30
121	+ 3 — 0	15

d. the temperatures measured differ by not more than 1°C during the last 5 minutes of the sterilization hold time (this indicates that excessive stratification is not occurring within the chamber);

e. the temperatures measured in the test bottles have fallen to 80°C[a] or below before the door interlock is released to allow the door to be opened on completion of the cycle (see A11.5 d.).

A11.11 It should be noted that the total heat energy input to the load over the whole sterilizing cycle and its effect on the product is a matter for the Quality Controller. However, only in exceptional cases will these problems be met in practice.

Additional requirements for the quarterly test

A11.12 The sterilizer should be loaded with test bottles to duplicate a batch for which a MTR has previously been established and which has been chosen (normally on a rotating basis with the other standard batches) for this particular test.

A11.13 Thermocouples should be inserted into the two bottles located in positions established during commissioning where they were slowest to heat up and slowest to cool down. A third thermocouple should be inserted in the drain line.

(a) This may be higher for non-rigid containers.

A11.14 The complete cycle temperatures should be recorded during a full automatic cycle for the selected test load, by a test instrument having a minimum of three channels.

Additional requirements for yearly, commissioning and re-commissioning tests

A11.15 Reference should be made to Appendix 4 on the selection of test loads. MTRs should be established after commissioning for all batch types to be processed by the sterilizer. These are required for production control purposes, the yearly and re-commissioning tests. The Sterilizer Engineer may apply his discretion in the choice of test loads for commissioning, yearly and re-commissioning tests and, in most cases, tests on two representative but dissimilar batch types will be sufficient.

A11.16 The sterilizer should be loaded with test bottles appropriate to the selected test load.

A11.17 Thermocouples should be inserted into bottles which are distributed at the eight corners of the load and in a bottle at the centre of the bottom layer. Two additional thermocouples should be inserted, the first in the chamber drain and the second within the upper third of the free chamber space.[b]

A11.18 The complete cycle temperature should be recorded during a full automatic cycle, by a test instrument having a minimum of 12 channels.

A11.19 Attempts to sterilize or disinfect the cooling water do not compensate for inadequately sealed containers nor for containers not designed for processing in rapid-cooled sterilizers. However, if the temperature characteristics of the spray cooling system are required to be known, an additional thermocouple may be inserted either in the spray water inlet pipe to the chamber, within 100 mm. of its entry to the chamber, or in the coldest position in the spray water hold tank.

A11.20 If the temperature of the spray cooling water has been recorded it should comply with the stated performance specification.

(b) The temperature distribution of fluids in sealed non-rigid containers should be ascertained during separate tests and thermocouples should be positioned accordingly.

Appendix 12

Performance tests for sterilizers for unwrapped instruments and utensils

General

A12.1 The tests required are those referred to in Appendix 4, the records of which are required for batch and day-to-day production control purposes. They are as follows:

a. weekly temperature and automatic process control test;

b. quarterly test;

c. yearly, commissioning and re-commissioning tests.

A12.2 For all these tests the sterilizer should be fully loaded with a mixed load of unwrapped instruments and utensils of the type normally processed. They should be conducted after a *warming up* cycle has been completed.

Weekly temperature and automatic process control test

A12.3 It is helpful if the sterilizer is fitted with a chart recorder, but this is not essential for satisfactory operation of the sterilizer or for performance of this test.

A12.4 The sterilizer should be operated under automatic control and the complete test cycle observed. At least three sterilizer instrument readings of chamber temperature and pressure should be taken at equal time intervals during the sterilization hold time. Observations should also be made of temperatures and pressures at other significant points of the cycle and the duration of the various stages or sub-stages of the cycle. An entry should be made in the Plant History Record of all these observations.

A12.5 The test should be considered satisfactory if all the following requirements are met:

a. the measured parameters are consistent with previously recorded test results (particular note should be made of the final vacuum level on machines having a vacuum drying stage);

b. the engineer observing the test does not detect any mechanical or other anomaly;

c. the load, when removed from the chamber, is sensibly dry.

Common requirements for quarterly, yearly, commissioning and re-commissioning tests

A12.6 Each of these tests requires that temperature measurements be recorded by separate thermometric equipment, using a minimum of two thermocouples. The thermocouples should be placed, one in the chamber drain within approximately 100 mm. of the exit from the chamber and the other in contact with the surface of a representative load item, e.g. by closing a pair of large forceps on to it. In the case of a small sterilizer having no drain, the former should be inserted in an appropriate position within the chamber air vent discharge pipe or adjacent to it.

NOTE: The thermocouple in the chamber drain should be in contact with condensate at the phase boundary condition. This may sometimes require deeper insertion than the recommended 100 mm.

A12.7 A temperature and automatic process control test should be carried out in association with these tests, and observations should be made as described under *Weekly Test* and recorded.

A12.8 The tests should be considered satisfactory if all the following requirements are met:

a. the temperatures in the drain and of the representative load item are within the limits of $134 \pm {}^{4}_{0}$°C during a continuous period of 3 minutes of Stage 2;

b. the temperature of the representative load item does not differ by more than 2°C from that of the chamber drain during that 3 minute period;

c. either of the following applies:

(i) the cycle is completed in not more than 10 minutes for those machines supplied with steam from an external source,

OR

(ii) it should be possible to complete 16 cycles within a period of 4 hours, for bench top machines having integral electrically heated elements. (It may not be necessary to complete 16 cycles in order to ensure that the sterilizer will pass this test. A sterilizer which completes 4 cycles from cold in one hour will clearly pass this test, but see A12.9.)

NOTE: It is anticipated that tests for small electrically heated bench top bowl and instrument sterilizers will not take place at the user site but that the sterilizer will be exchanged for a spare machine and will be removed to a suitable central location for maintenance and test purposes.

Yearly, commissioning and re-commissioning tests

A12.9 The alternative test at A12.8 c.(ii) should, ideally, be continued for the full 4 hours to ensure that the temperature of the water in the reservoir does not exceed 90°C with an ambient air temperature of between 20°C and 25°C. If the rate of temperature rise is observed to be satisfactory (say 3°C or 4°C per cycle) the tests may be discontinued after 3 or 4 cycles. This does not apply to reservoirs within the chamber.

A12.10 A third thermocouple should be inserted into the upper third of the free chamber space for detecting superheat.

A12.11 The limits for superheating are given in Appendix 1.

Appendix 13

Performance tests for hot air sterilizers

A13.1 There are two tests for hot air sterilizers:

a. Basic Performance Test,

b. Production Load Test.

A13.2 The manufacturer should certify that the sterilizer has satisfactorily passed the Basic Performance Test.

A13.3 The Sterilizer Engineer should witness any tests performed on site by the manufacturer.

A13.4 The Basic Performance Tests should be carried out by the Sterilizer Engineer:

a. after any modification which may affect performance;

b. when the Production Load Test result has proved unsatisfactory.

NOTE: An unsatisfactory loading pattern may result in a sterilizer failing the Production Load Test but passing the Basic Performance Test; individual load items or containers should be disposed within the chamber in a manner which permits good air circulation. In such cases it will be necessary to redistribute the load and carry out additional tests until a loading pattern is established which enables the sterilizer to pass the Production Load Test.

A13.5 If the results of the Basic Performance Test are unsatisfactory the Department should be advised, in accordance with HSC(IS)41 (30).

A13.6 The Sterilizer Engineer should carry out the Production Load Test on all sterilizers, to establish the heat up time and to prepare the MTR.

A13.7 A 12-channel recorder is normally adequate for both tests; one thermocouple should either be attached or close to the sensor which serves the sterilizer chart recorder and a second should either be attached or close to the sensor for the sterilizer thermometer. The remaining 10 thermocouples are located at test positions disposed throughout the load.

Basic performance test

A13.8 The Basic Performance Test is that described in B.S.3421—Specification for Performance of Electrically Heated Sterilizing Ovens (14).

NOTES:

a. 1 lb. (454 g.) jam jars and 10 oz. (280 g.) pickle jars are suitable alternatives to the 120 mm. high, 60 mm. diameter glass jars specified in the B.S.3421.

b. The test liquids specified in the British Standard are difficult to obtain. A suitable non-flammable, non-toxic silicone fluid can be obtained from Hopkin and Williams, P.O. Box 1, Romford, Essex. The fluid is *dark brown dimethylpolysiloxane product No. 17*, which is available in 500 g. and 5 kg. containers.

Production load test

A13.9 In general a MTR may be established for the worst case load, i.e. that which will require the longest time to reach the sterilizing temperature throughout. If the worst case MTR is used for smaller loads they may well be held at the sterilizing temperature for prolonged periods. In the majority of cases the extra time at temperature will not affect the items processed and the extended time will not, therefore, be a practical disadvantage. Where prolonged heating can cause deterioration of load items (e.g. certain medicinal products) they should be processed by a separate operating cycle with its own specific MTR.

A13.10 The test should be performed with the worst case load (and any specific load) for which the sterilizer is to be used.

A13.11 Two thermocouples are located as in paragraph A13.7. For the remaining 10 thermocouples a series of preparatory tests may be required to establish which specific items within the test load show the widest temperature variation; these will normally be at the corners of the chamber and at the centre of each shelf. Once a distribution pattern for the thermocouples has been established it should be used in all subsequent tests for that load type.

A13.12 If the load consists of non-volatile fluids, or powders, the thermocouples should be inserted through the caps or lids of the containers so as to be at the centre of the contents. If the load consists of glass ampoules the thermocouples should be inserted into them and sealed in position by means of a heat stable sealant, e.g. *Araldite*.

A13.14 If the load item is an instrument in a container, the thermocouple should be in intimate contact with the instrument.

A13.15 The multichannel recorder should monitor a complete cycle in each of the tests.

A13.16 The parameters are defined as follows:

a. *Temperature overshoot*

It is first necessary to identify the *steady state* period. The steady state period is the first total period of 30 minutes during which the temperature varies by no more than 1°C. Under certain conditions the

temperature before the steady state has been reached is greater than the steady state average; when this occurs the difference between the maximum temperature attained and the steady state average is the *temperature overshoot* (see Figure A13.1).

NOTE: Temperature *overshoot* as defined in B.S. 3421 should be used as a guide for establishing MTRs. In practice it may be found that the 2°C limit may be exceeded by virtue of the load distribution. The disposition of load items should not however result in overshoot in excess of 5°C.

b. *Temperature drift*

After the first 30 minutes of the steady state period the recording may be discontinued for 90 minutes to avoid wasting the chart, after which the recording should be re-commenced for a further period of 30 minutes. The difference between the average of the temperatures recorded during the two separate 30 minute periods is the *temperature drift* during a 120 minute period (see Figure A13.1).

c. *Reproducibility of chamber temperature*

The sterilizer should be switched off from the steady state condition, allowed to cool for at least 6 hours and switched on again without further temperature adjustment for at least 2½ hours, and the temperature should be measured again to determine *reproducibility*.

d. *Temperature variation*

The temperature measured by the thermocouple in contact with the sterilizer chart recorder element is recorded (see A13.17 b.). The temperature variation is the difference between that temperature and each of the temperatures measured by means of the ten thermocouples disposed within the load, disregarding the sign (see Figure A13.2).

A13.17 The parameters are determined by a method based on B.S.3421 (14) as follows:

a. Temperature overshoot, temperature drift and reproducibility: these are obtained from measurements of the chamber temperature only, made by means of the thermocouple in contact with the chamber chart recorder sensor.

b. Temperature variation is measured by means of the ten thermocouples disposed within the load at the locations which show the widest temperature variation, and the thermocouple in contact with the chart recorder sensor.

A13.18 The Production Load Test should be considered satisfactory if all the following requirements are met:

a. the temperature overshoot does not exceed 2°C;

b. the temperature drift does not exceed 1°C;

c. the temperature variation for any of the ten locations and the indicating thermometer sensor does not exceed 5°C within the period of at least 60 minutes after the whole of the load has reached the sterilizing temperatures;

d. in a repeat test, the chamber temperatures as indicated by the thermocouple attached to the sensor of the sterilizer chart recorder and the thermocouple attached to the sensor of the sterilizer thermometer are reproduced to within 1°C of their previous reading (the tests to determine reproducibility may be performed independently with an empty chamber);

e. when tested during a separate test the overheat cut-out operates satisfactorily.

NOTE: This test may be carried out with an empty chamber and either by setting the chamber control thermostat above 200°C or by preventing its operation. The temperature is measured in this test by means of the thermocouple in contact with the chart recorder element.

A13.19 Tests to determine all these parameters may be performed simultaneously, therefore, if the recorder is of the multi-channel *dotting* type; care is required when scrutinizing the resultant traces. For each of these tests it is necessary to identify separately the trace obtained from the thermocouple attached to the sterilizer chart recorder sensing element.

A13.20 All the multi-channel recorder charts should be retained as part of the commissioning documents. These records should include details of the *worst case* test load as follows:

a. type of product;

b. size, volume and type of container or wrapping material;

c. number of product items;

d. distribution within the chamber;

e. shelving system used;

f. location of thermocouples used in the test to establish the MTR.

Establishing the MTR

A13.21 The TRC obtained during the final satisfactory worst case load test can be used for the production of MTR.

A13.22 The MTR should be annotated to show the details in A13.20 and:

a. the description of the worst case load;

b. the thermostat setting to ensure all parts of the load reach temperature and to account for temperature variation (the coldest load item may be 5°C below the temperature recorder on the MTR);

c. the timer setting to ensure heat-up of all load items and exposure to the sterilizing temperature for the appropriate time.

NOTE: Tests undertaken to establish a MTR should be commenced with the sterilizer and load temperatures within 2°C of ambient temperature.

A13.23 The number of MTRs required is a matter for agreement between the Sterilizer Engineer and the User. Only one MTR should be in use for each sterilizer unless products are likely to be adversely affected by extended heating (see A13.9).

Half-yearly test

A13.24 For this test a 3-channel temperature recorder may be used and the test should be performed using the worst case load for which the MTR has been established.

A13.25 Two thermocouples should be placed as in paragraph A13.7, the third being used to measure the temperature of a load item located in one of the positions used during the commissioning tests.

A13.26 The test should be considered satisfactory if all the following requirements are met:

a. the test requirements of paragraph A13.18 are met (except for item c.);

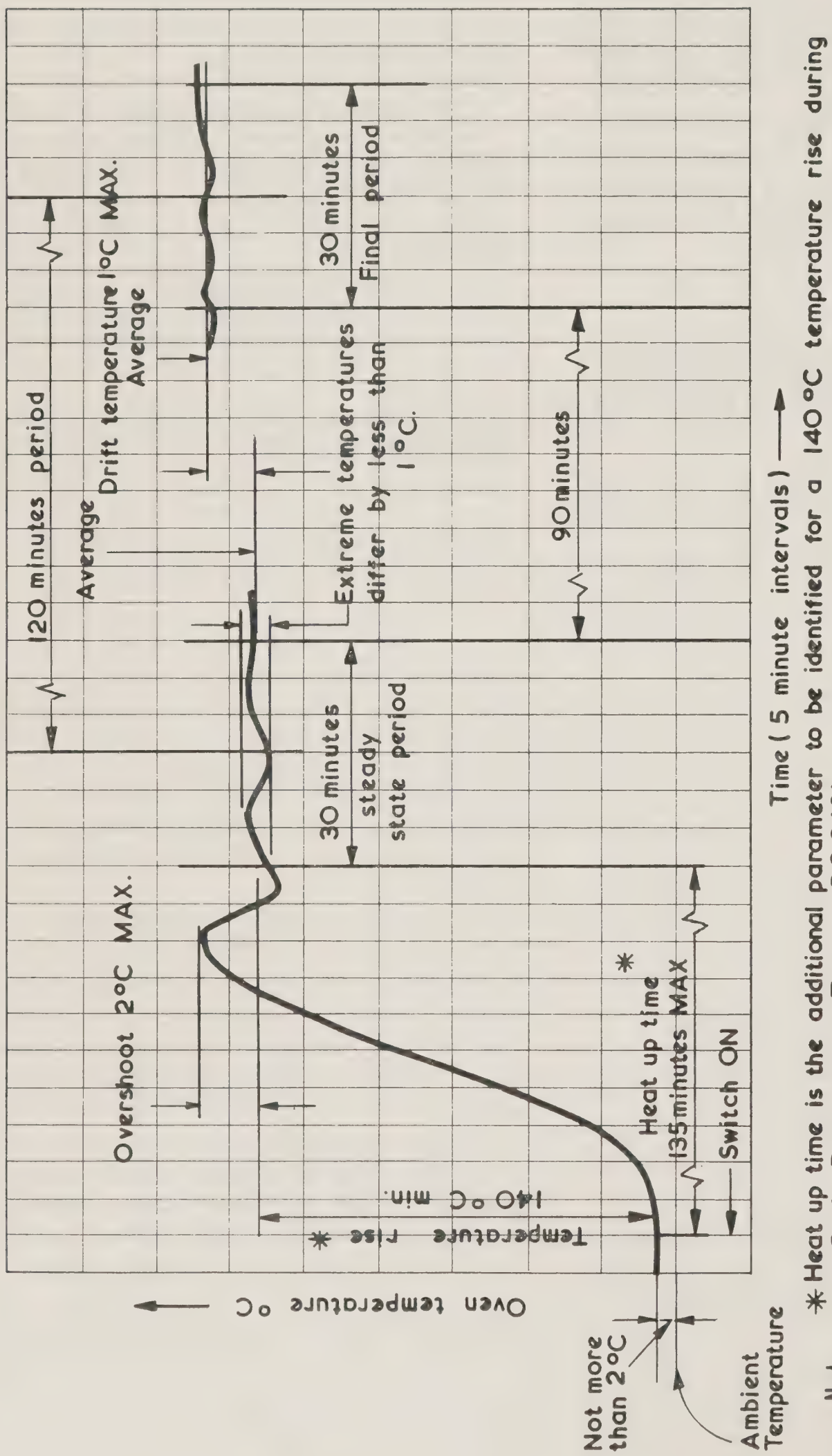
b. the temperature of the load item is within 2°C of the temperature measured at the same position during the commissioning or re-commissioning tests.

Yearly test

A13.27 For this test a 12-channel recorder is required and the test should be conducted with the worst case load for which the MTR was established.

A13.28 The test should be considered satisfactory if all the requirements of paragraph A13.18 are met.

Figure A 13.1

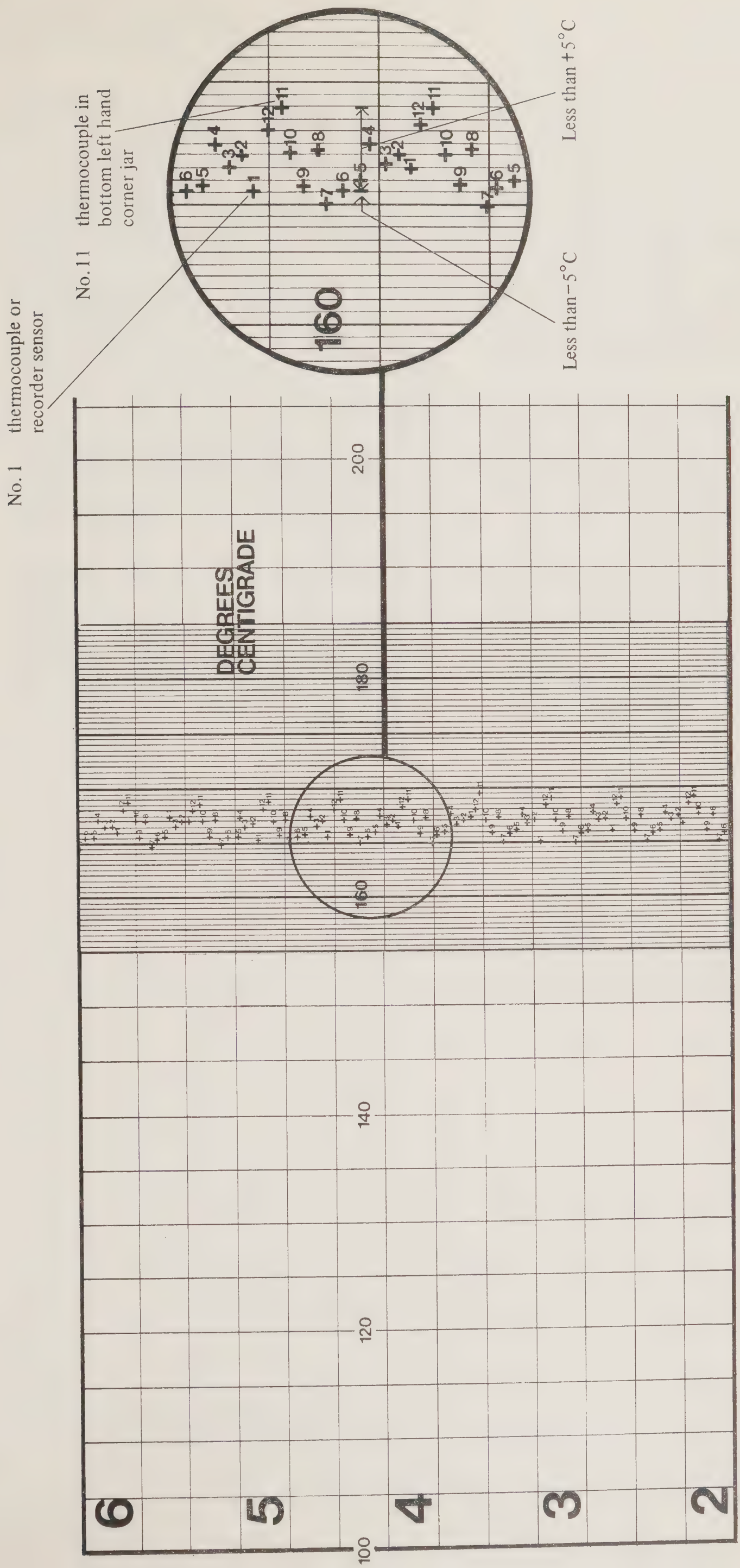


* Heat up time is the additional parameter to be identified for a 140 °C temperature rise during a Basic Performance Test to B.S. 3421.

Note

1) The recording will normally be that obtained from a multi-channel 'dotting' instrument which will also show the test jar thermocouple temperatures.
2) The illustration represents the recording obtained from the thermocouple in contact with the sterilizer chart recorder sensing element, and indicates which significant parameters require to be identified.
3) The illustration shows both overshoot, and ripple, neither of which may be evident in a test because of thermal hysteresis effects.

Figure A 13.2



This shows a typical (good) 12 channel recording and shows the distribution of test jar temperatures.

In this test the temperature variation was +3·5° C and −0·5° C. A temperature variation of ±5° C is acceptable.

Appendix 14

Master Temperature Record

A14.1 A typical Master Temperature Record is shown in Figure A14.1. This is a copy of the chart from the sterilizer chart recorder. A simultaneous temperature recording using a 12-channel chart recorder was used to validate the MTR; the 12-channel chart recording showed that the temperatures of fluid in the test bottles varied between 116°C and 118°C at the start of the sterilization hold time. These temperatures were maintained within the sterilization temperature limits for a period of 30 minutes, and during the last 5 minutes of the 30 minute hold time were all within 1°C.

A14.2 The sensor of the sterilizer recorder responded to the temperature at one point, in this case the chamber drain; the MTR is therefore an analogue, representing a time/temperature profile of a satisfactory sterilization cycle, with which all subsequent production load TRCs for similar loads can be compared.

A14.3 The TRC shown in Figure A14.2 was obtained for a production load. It can be seen that correlation with the MTR is good and the sterilization cycle was considered satisfactory.

A14.4 The TRC for the production load shown in Figure A14.3 indicates that the cycle was not satisfactory. The drain line temperature, i.e. the temperature recorded on the TRC, failed to reach the acceptable level, and it is reasonable to assume that most, if not all, of the fluids in this load similarly failed to reach the acceptable temperature, since the relationship between drain line temperature and bottle contents temperature with this type and size of load was established during commissioning. The load was rejected for this reason.

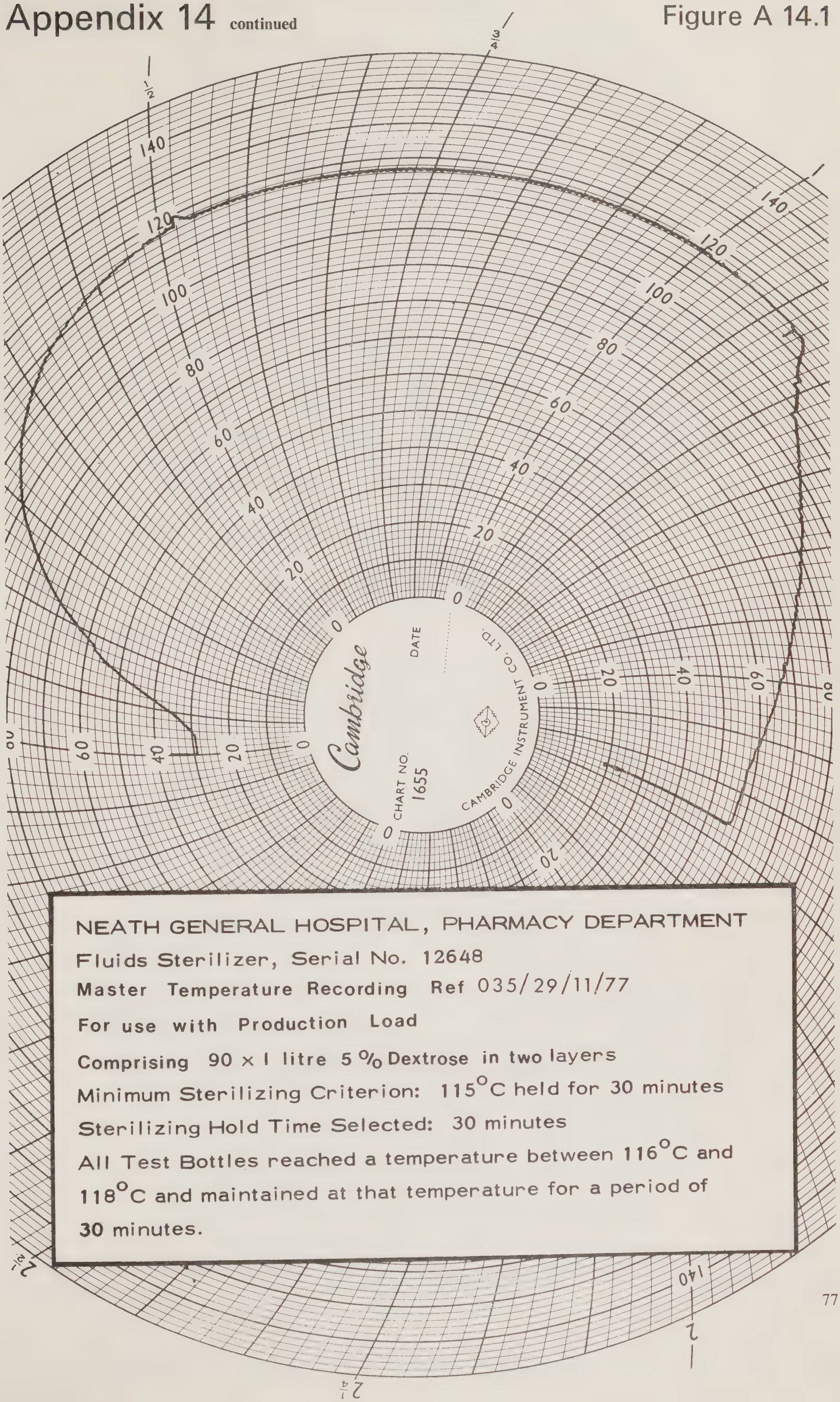
A14.5 The MTR should be produced from a TRC of a load which was initially at ambient temperature. Two or three TRCs should be obtained with such loads and the one showing the shortest time at sterilizing temperature should be used for producing the MTR.

NOTES:

a. The original MTR transparency used for the production of Figure A14.1 in this document was produced by a photographic method. Any method of producing a transparency is suitable provided the size is not distorted.

b. A Xerox process using 7000T/POS transparency material, produced by a Flat Plate Camera, is a suitable method, provided the original record is made with black ink. The result is a bold temperature trace, even with a faded chart background. There is also an acceptable MMM process, using their copying machine.

Figure A 14.1



NEATH GENERAL HOSPITAL, PHARMACY DEPARTMENT

Fluids Sterilizer, Serial No. 12648

Master Temperature Recording Ref 035/29/11/77

For use with Production Load

Comprising 90 x 1 litre 5 % Dextrose in two layers

Minimum Sterilizing Criterion: 115°C held for 30 minutes

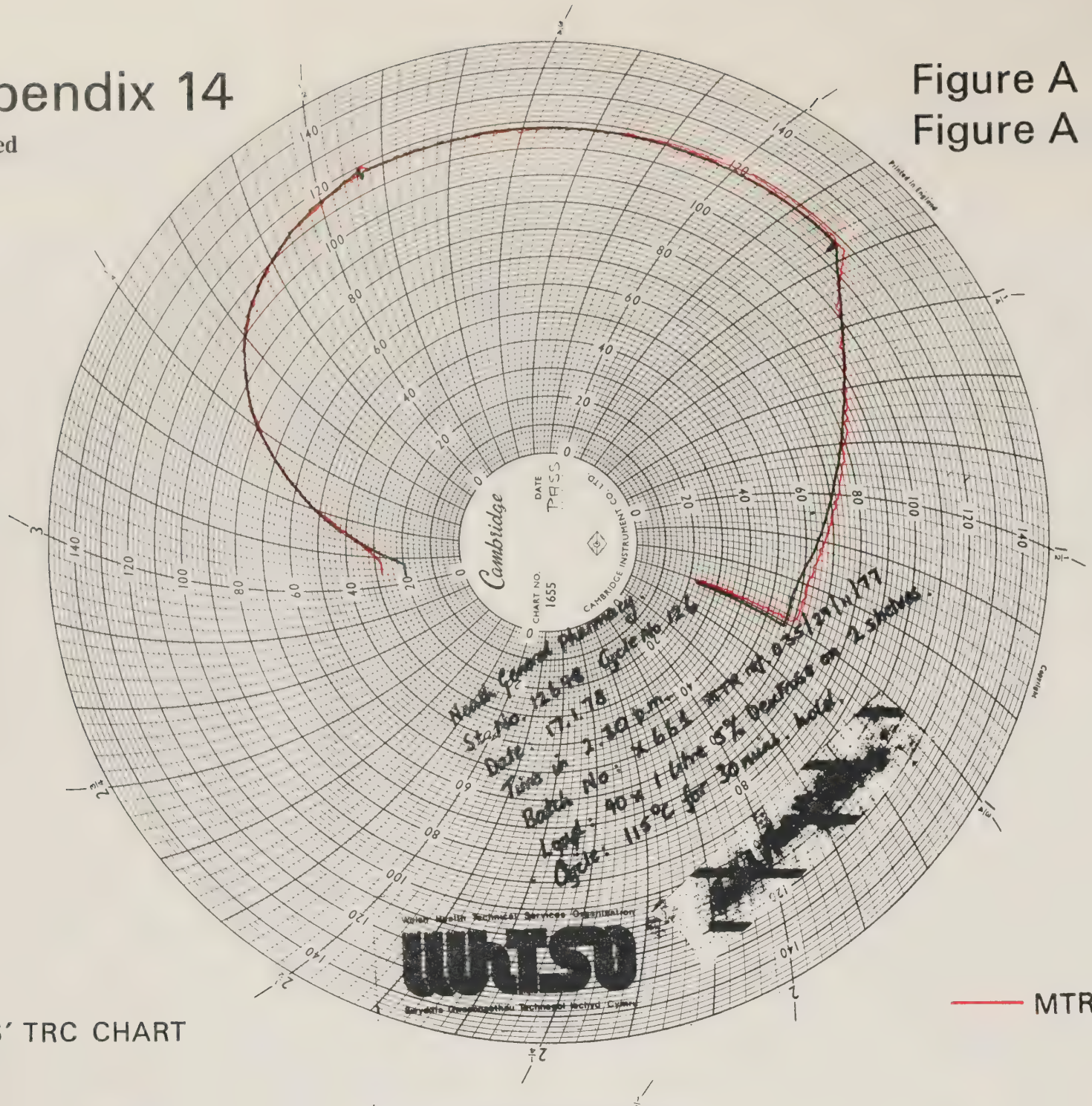
Sterilizing Hold Time Selected: 30 minutes

All Test Bottles reached a temperature between 116°C and 118°C and maintained at that temperature for a period of 30 minutes.

Appendix 14

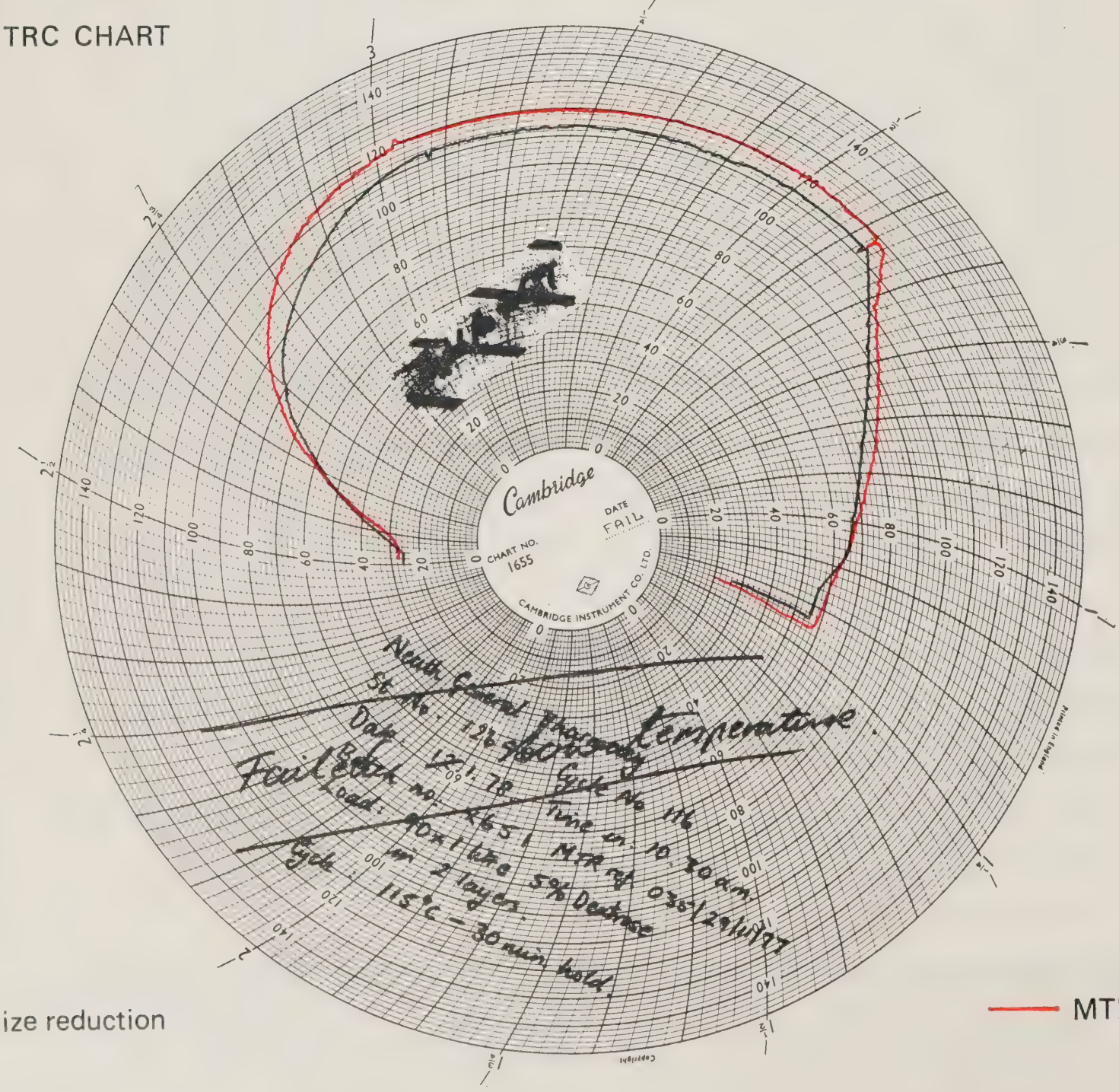
continued

Figure A 14.2
Figure A 14.3



'PASS' TRC CHART

MTR trace



'FAIL' TRC CHART

Half-size reduction

MTR trace

NOTE: For ease of presentation the MTR Transparency overlay is not printed separately; the MTR Trace is shown in red superimposed on the TRC Charts.

Appendix 15

MAINTENANCE CERTIFICATE

(See Appendix 4, paragraph A4.24)

Section 1

Identity of Sterilizer:
(e.g. type, make, location and identification number)

.....

.....

.....

.....

.....

Section 2

Maintenance work and tests have been completed in accordance with the appropriate *Weekly/Three-weekly/ Six-weekly/Quarterly/Half-yearly/Yearly/Two-yearly/Three-yearly procedure, and this sterilizer is *fit/unfit for use, subject to any limitation stated below.

.....

.....

.....

.....

Signed.....*Maintenance Engineer.* *Date*.....

NOTE 1: Section 1 is not required when this Certificate is entered in the form of Section 2 in a Plant History Record which is freely accessible to the User.

*Delete as appropriate in Section 2.

Appendix 16

BIBLIOGRAPHY

1. Department of Health and Social Security. Report of the Working Party on the laboratory use of dangerous pathogens. Chairman: Sir George Godber. HMSO, 1975, 40 pp. (Cmnd. 6054.)

2. Department of Health and Social Security. Guide to good pharmaceutical manufacturing practice, 1977. HMSO, 1977, 52 pp.

3. Central Health Services Council. Joint Committee on central sterile supply departments report. Chairman: Sir Edward Collingwood. Ministry of Health, 1967, 15 pp. ("Collingwood Report")

4. Department of Health and Social Security. National Health Service central sterile supply departments. DHSS, 1967, 2 pp. (HM(67)13.)

5. Department of Health and Social Security. Report of the committee appointed to inquire into the circumstances, including the production, which led to the use of contaminated infusion fluids in the Devonport Section of Plymouth General Hospital. Chairman: C. M. Clothier. HMSO, 1972, 33 pp. (Cmnd. 5035.)

6. Health and Safety at Work, etc., Act 1974. (Ch. 37.) HMSO, 1974, 117 pp.

7a. Medicines Act 1968. (Ch. 67.) HMSO, 1968, vi, 165 pp.

7b. Medicines Act 1971. (Ch. 69.) HMSO, 1971, 2 pp.

8. Department of Health and Social Security and Welsh Office. Estmancode, Estate Management (Building, Engineering and Grounds) Practices Code for the National Health Service. DHSS, loose leaf binder.

9. Ministry of Health. Planned preventive maintenance: a system for engineering plant and services. HMSO, 1965, 40 pp. (Hospital Technical Memorandum 13.)

10. Department of Health and Social Security. Preventive maintenance manual: electrical. DHSS, amended 1977, loose leaf binder. (Estmancode PMG/12.)

11. Department of Health and Social Security. Preventive maintenance manual: mechanical. DHSS, amended 1977, loose leaf binder. (Estmancode PMG/13.)

12. Department of Health and Social Security. Operating department. HMSO, 1967 (reprinted 1975), 47 pp. (Hospital Building Note 26.)

13. B.S.2646: 1955. Copper laboratory autoclaves. British Standards Institution, 1955, 16 pp. Amendment PD 5771, February 1966.

14. B.S.3421: 1961. Performance of electrically heated sterilizing ovens. British Standards Institution, 1961, 8 pp.

15. B.S.3970: Part 1: 1966. Sterilizers for porous loads. British Standards Institution, 1966, 20 pp. Amendment AMD 304, August, 1969.

16. B.S.3970: Part 2: 1966. Sterilizers for bottled fluids. British Standards Institution, 1966, 16 pp.

17. B.S.3970: Part 3. Not published. Draft issued for comment.

18. B.S.3970: Part 4. Not published. Draft issued for comment.

19. B.S.3970: Part 5: 1968. Electrically heated steam generators for use with hospital sterilizers. British Standards Institution, 1968, 16 pp.

20. Ministry of Health. Central sterile supply department. HMSO, 1961 (reprinted 1963), 7 pp. (Hospital Building Note 13.)

21. B.S. 4196: 1967. Guide to the selection of methods of measuring noise emitted by machinery. British Standards Institution, 1967, 16 pp.

22. Department of Employment and Productivity. Electrical limit switches and their applications. HMSO, 1970, 36 pp. (Health and Safety at Work 24.)

23. Institution of Electrical Engineers. Regulations for the electrical equipment of building. 14th edition, 1966, reprinted. Institution of Electrical Engineers, 1967, vii, 224 pp.

Appendix 16 continued

24. B.S.6231: 1969. PVC-insulated cables for switchgear and control gear wiring. British Standards Institution, 1969, 16 pp.
Amendment AMD 1406, April 1974.

25. Building Regulations 1976. HMSO, 1976, 308 pp. (Statutory Instrument 1976, No. 1676.)
Clause E15, pp. 86–89.

26. B.S.4275: 1974. Recommendations for the selection, use and maintenance of respiratory protective equipment. British Standards Institution, 1974, 24 pp.

27. Department of Health and Social Security. Cold water supply: storage and mains distribution. 1978, 74 pp. (Health Technical Memorandum 27.)

28. Department of Health and Social Security. Health building engineering installations: commissioning and associated activities. New edition. HMSO, 1978, 6 pp. (Health Technical Memorandum 17.)

29. Department of Health and Social Security. Engineering Division. Mechanical and electrical, plant and services defect and failure report. DHSS, one sheet only.

30. Department of Health and Social Security. The reporting of accidents with, and serious defects in, medicinal products and other medical supplies and equipment. DHSS, 1974, 5 pp. (HSC(IS)41.)

31. Department of Health and Social Security. Hospital service engineering, 1976, June, No. 30.

32. Medical Research Council. The sterilization, use and care of syringes. Working party on sterilization of syringes, Feb. 11, 1962. Revision of War Memorandum No. 15. Medical Research Council, 1962, 26 pp. (Memorandum No. 41.)

33. Department of Health and Social Security. British pharmacopoeia. 1973. HMSO, 1978, xxii, 120 pp.

34. B.S.2648: 1955. Performance requirements for electrically-heated laboratory drying ovens. British Standards Institution, 1955, 12 pp.
Amendments PD 2517, June 1956.

35. Department of Health and Social Security. Protection of condensate systems: filming amines. Revised edition. HMSO, 1970 (revised 1978), 2 pp. (Health Technical Memorandum 6.)

36. Lyle, O. The efficient use of steam; written for the Fuel Efficiency Committee of the Ministry of Fuel and Power. HMSO, 1947, 912 pp.

37. Henry, P. S. H. Physical aspects of sterilizing cotton articles by steam. *Journal of Applied Bacteriology*, 1959, vol. 22, no. 1, pp. 159–173.

38. B.S.5164: Indirect acting electrical indicating and recording instruments and their accessories. British Standards Institution, 1975, 36 pp.

39. B.S.1904: 1964. Industrial platinum, resistance thermometer elements. British Standards Institution, 1964, 28 pp.
Amendments PD 6258, September 1967; AMD 426, February 1970.

40. B.S.1041: Part 4: 1966. Thermocouples. British Standards Institution, 1966, 40 pp.

41. B.S.4937: Part 3: 1973. Iron/copper-nickel thermocouples. Type J. British Standards Institution, 1973, 16 pp.

42. B.S.4937: Part 4: 1973. Nickel-chromium nickel-aluminium thermocouples. Type K. British Standards Institution, 1973, 16 pp.

43. B.S.4937: Part 5: 1974. Copper/copper-nickel thermocouples. Type T. British Standards Institution, 1974, 12 pp.

44. B.S.5235: 1975. Dial-type expansion thermometers. British Standards Institution, 1975, 12 pp.

45. B.S.1704: 1951. General purpose thermometers. British Standards Institution, 1951, 12 pp.
Amendments PD 2932, December 1957; PD 3717, March 1960; AMD 1151, May 1973.

46. B.S.1780: Part 2: 1971. Metric units—British Standards Institution, 1971, 56 pp.
Amendment AMD 1155, April 1973.

47. B.S.593: 1974. Laboratory thermometers. British Standards Institution, 1974, 20 pp.

Appendix 16 continued

48. B.S.1828: 1961. Reference tables for copper *v.* constantan thermocouples. British Standards Institution, 1961, 20 pp.
Amendment AMD 406, January 1970.

49. Department of Health and Social Security. Application of Medicines Act to Health Authorities. DHSS, 1975. (Health Service Circular (Interim series) 128.)

50. Department of Health and social security. Plant history record. DHSS, revised 1975. (Estmancode Form PMG/8.)

51. Health and Safety Executive. Factory Forms. Steam Boiler—cold. HMSO. (Form No. F55.)
Examination of plant required under S.33 of the Factories Act 1961.

52. Health and Safety Executive. Factory Forms. Steam Boiler—under pressure (also for economizer and super heater). HMSO. (Form No. F55A.)
Examination of plant required under S.33 of the Factories Act 1961.

53. Health and Safety Executive. Factory Forms. Steam Receiver. HMSO. (Form No. F58.)
Examination of plant required under S.35 of the Factories Act 1961.

54. Bowie, J H, Kelsey, J. C. and Thompson, G. R. The Bowie and Dick autoclave tape test. *Lancet*, 1963, March 16, vol. i, pp. 586–587.

55. B.S.1781: 1967. Linen textiles for use by government departments, hospitals and local authorities. British Standards Institution, 1967, 20 pp.
Amendments AMD 1037, December 1972: AMD 1587, October 1974.

56. B.S.1781P: 1967. Standard patterns for linen textiles for use by government departments, hospitals and local authorities. British Standards Institution, 1967.

57. B.S.3281: 1960. Rectangular metal boxes for use in high vacuum steam sterilizers. British Standards Institution, 1960, 8 pp.

LIBRARY AND INFORMATION SERVICE
POLYTECHNIC OF NORTH LONDON
HOLLOWAY ROAD
LONDON N7 8DB

Printed in Wales for Her Majesty's Stationery Office
by Qualitex Printing Limited Cardiff

Dd. 597442 K40 4/79

C1/SFB (1979)
4 (8-)

© *Crown copyright* 1980

First published 1980

HER MAJESTY'S STATIONERY OFFICE

Government Bookshops

49 High Holborn, London WC1V 6HB
13a Castle Street, Edinburgh EH2 3AR
41 The Hayes, Cardiff CF1 1JW
Brazennose Street, Manchester M60 8AS
Southey House, Wine Street, Bristol BS1 2BQ
258 Broad Street, Birmingham B1 2HE
80 Chichester Street, Belfast BT1 4JY

Government Publications are also available through booksellers

ISBN 011 320458 2